85-836

No. ____

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

GEL SPICE COMPANY, INC.
and BARRY ENGEL,

Petitioners,

—vs.—

UNITED STATES OF AMERICA,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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QUESTION PRESENTED FOR REVIEW

Does the confrontation clause of the sixth amendment prohibit the government from using documents for an evidentiary purpose that were withheld pursuant to a claim of privilege and never made available to the defendant?

PARTIES

Petitioners are Gel Spice Company, Inc., a New York corporation,[1] and Barry Engel. Respondent is the United States of America.

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1 Rule 28.1 statement: Gel Spice Company, Inc. has no parent companies, subsidiaries or affiliates.

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UNITED STATES OF AMERICA,

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Petitioners, Barry Engel and Gel Spice Company, Inc., respectfully petition this Court for a writ of certiorari to review the opinion and judgment of the United States Court of Appeals for the Second Circuit which was entered on September 13, 1985.

OPINIONS BELOW

The opinion of the court of appeals is not yet reported. The relevant opinions of the district court are reported at 601 F. Supp. 1205 (E.D.N.Y. 1985) and 601 F. Supp. 1214 (E.D.N.Y. 1985).

JURISDICTION

The decision of the court of appeals was entered on September 13, 1985. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1)(1983).

RELEVANT CONSTITUTIONAL PROVISION

The Confrontation Clause of the Sixth Amendment to the United States Constitution provides:

> In all criminal prosecutions, the accused shall enjoy the right . . . to be confronted with the witnesses against him. . . .

STATEMENT OF THE CASE

On December 21, 1984, petitioners Gel Spice Company, Inc. (Gel Spice) and Barry Engel, president of Gel Spice, were convicted by the United States District Court for the Eastern District of New York (McLaughlin, J.) of ten counts of violating the Food, Drug and Cosmetic Act, 21 U.S.C. § 342(a)(4)(1983). Petitioners timely appealed to the United States Court of Appeals for the Second Circuit which affirmed the Eastern District's decisions on all counts.

Gel Spice, Barry Engel, and his brother Andre Engel, who was later found not guilty on all counts, were charged by information filed in the Eastern District in December, 1980. Petitioners filed a motion in April 1981, seeking to suppress evidence and dismiss the information. Petitioners alleged that the government had made the decision to prosecute them about March 1973, following inspections of their facilities made in 1972. Petitioners asserted that because the government's "institutional posture" had shifted from the civil investigation of Gel Spice toward the investigation of the company with an eye toward criminal prosecution, evidence gathered in investiga-

tions taking place in July 1976, March 1977, July 1977, and January 1979 should be suppressed. Under the authority of *Abel v. United States*, 362 U.S. 217, *reh. denied*, 362 U.S. 984 (1960), it was improper for these ostensibly-civil investigations to be used to gather evidence for a criminal prosecution.

In April 1982, the case was referred by Judge Joseph M. McLaughlin to Magistrate Simon A. Chrein for fact-finding. The magistrate found that Petitioners has raised sufficient factual questions to entitle them to a hearing on the issue of the government's bad faith.

The magistrate subsequently reviewed *in camera* documents that the government had refused to disclose after claiming the protection of the internal memorandum exception of Federal Rule of Criminal Procedure 16(a)(2). On the basis of this *in camera* review, the magistrate found that the government had not investigated Gel Spice in bad faith and that the institutional decision to prosecute was made in September 1978. The magistrate then concluded he need not hold an evidentiary hearing on the bad faith issue, nor need he disclose the allegedly-privileged documents to Petitioners.

Following vehement objections by Petitioners' trial counsel at a hearing dated June 29, 1982, the magistrate asked the parties to brief the issue of whether Petitioners had been deprived of their sixth amendment confrontation rights by his actions. In a colloquy with counsel the magistrate admitted that Petitioners' sixth amendment rights had indeed been violated because he had based his findings upon documents whose contents had been concealed from Petitioners. The magistrate stated that it was improper for him to make a factual finding based upon evidence about which the petitioners had been "kept in the dark." In an interim report and recommendation dated December 13, 1982, the magistrate vacated his earlier findings and held that an evidentiary hearing on the bad faith question was necessary.

Instead of defending against Petitioners' assertions in an adversarial hearing, the government submitted a document entitled "Government's Proffer of Alternative Modes for Showing That Inspections in Question Were Not Undertaken Solely for a Criminal, Evidence-Gathering Purpose." This proffer consisted of the affidavits of two government officials. The affidavit of Frederick W. Blumenschein, a Compliance Officer with the FDA, purported to show that the 1973 prosecution recommendation was "withdrawn" and not "held in abeyance" as Petitioners had claimed. Blumenschein admitted in this affidavit that his statements were based solely upon "information in official agency files to which I have access." These are the very documents that Petitioners were not allowed to see!

Based on the affidavit, the magistrate reinstated his earlier findings that the investigations had not been conducted in bad faith and that the "institutional decision to prosecute" had been made in September 1978. In addition, the magistrate summarily concluded that petitioners had not made a sufficient showing of bad faith to warrant an evidentiary hearing, this despite the fact that he had found a sufficient showing of bad faith on two earlier occasions.

Even though these findings of fact were based upon documents that the Petitioners, in violation of their sixth amendment rights, were never allowed to see, Judge McLaughlin accepted the magistrate's findings *in toto* and further stated that, based on his *de novo* review of the documents, he could find nothing in them that would support the Petitioners' allegations. On appeal, the court of appeals dealt with the sixth amendment question by avoiding it.

Although this was the main issue raised by the Petitioners on appeal, the court of appeals did not even mention the issue in its opinion. Rather, it held that even if the government's bad faith was a valid issue, the affidavits provided by the government adequately explained the disposition of the government's 1973 prosecution recommendation. The court of appeals sim-

ply ignored the fact that these affidavits were merely redactions of the secret government documents, and that the relevant factual finding was based on evidence about which petitioners had been "kept in the dark."

REASONS FOR GRANTING THE WRIT

THIS CASE PRESENTS AN IMPORTANT ISSUE OF FEDERAL LAW AND THE DECISION OF THE SECOND CIRCUIT IS CONTRARY TO DECISIONS OF THIS COURT, AND THE COURTS OF APPEALS FOR THE SIXTH AND SEVENTH CIRCUITS, AS WELL AS TO PRIOR DECISIONS OF THE SECOND CIRCUIT ITSELF

This case presents an extremely important question of constitutional law. Simply stated, the court of appeals held that, in a criminal case, the prosecution may withhold evidence from the defendant pursuant to a claim of governmental privilege and then use that same evidence, shielded from cross-examination as a result of the government's assertion of privilege, to support an essential factual finding. The decision of the court of appeals is contrary to decisions of this Court interpreting the sixth amendment, and to decisions of the sixth and seventh circuits, the New York Court of Appeals, and prior decisions of the Second Circuit itself.

This Court has never decided whether the sixth amendment right of confrontation prohibits the prosecution from using evidence that has been withheld from the defense pursuant to a claim of privilege to establish an essential element of the government's case. It is abundantly clear, however, from decisions of the courts of appeals and this Court's own opinions on the right of confrontation, that the sixth amendment compels disclosure to the defendants of all evidence that the government uses to support its case in chief.

Ironically, the leading case on point is the Second Circuit's own decision in *United States v. Coplon*, 185 F.2d 629 (2d Cir.

1950), *cert. denied*, 342 U.S. 920 (1952). In *Coplon*, the court of appeals held that it was a violation of the sixth amendment for the trial judge to refuse to let the defense see allegedly-privileged evidence, on the basis of which, after an *in camera* review, the judge had made an essential factual finding. 185 F.2d at 637-39. *See also United States v. Beekman*, 155 F.2d 580 (2d Cir. 1946); *United States v. Andolschek*, 142 F.2d 503 (2d Cir. 1944). This Court should take this opportunity to affirm *Coplon* as a basic limitation on the use of an evidentiary privilege as both "a sword and a shield." *See, e.g., United States v. Rylander*, 460 U.S. 752, *reh. denied*, 462 U.S. 1112 (1983).

Although this Court has never expressly held that the sixth amendment prohibits the affirmative use of evidence withheld pursuant to a claim of privilege, this principle flows directly from the rationale of the sixth amendment as spelled out by this Court in *Douglas v. Alabama*, 380 U.S. 415, 418-19 (1965) (quoting *Mattox v. United States*, 156 U.S. 237, 242 (1895)):

> The primary object of the constitutional provision in question was to prevent depositions or *ex parte* affidavits . . . being used against the prisoner in lieu of a personal examination and cross-examination of the witness . . . .

In *Douglas*, the prosecution read into the record a confession made by the petitioner's codefendant. The petitioner was not able to cross-examine the codefendant about the confession because the codefendant asserted the fifth amendment privilege against self-incrimination. The prosecution managed to get the confession into the record under the guise of cross-examining the codefendant as a hostile witness knowing that the witness would assert his fifth amendment privilege. Here the government, with the generous assistance of the trial court, used the guise of the internal memorandum privilege to get a one-sided interpretation of its evidence into the record in the form of affidavits based solely upon documents withheld from the Petitioners.

This Court has established that the underlying function of the confrontation clause is to ensure that the defendant has an effective means to test adverse evidence. *Ohio v. Roberts*, 448 U.S. 56, 63-64 (1980). In *Roberts*, this Court allowed the admission of the preliminary hearing testimony of an unavailable witness because the testimony had been subjected to cross-examination at the earlier hearing. Because the prior testimony had been subject to confrontation by the defendant, it bore sufficient indicia of reliability to be used as evidence. The defense had the opportunity to at least shed a light on the testimony different than that cast by the prosecution. *Id.* at 73. Here, on the other hand, Petitioners had no chance to lend their interpretation to the suppressed documents used by the trial court to conclude that no institutional commitment to prosecute Petitioners had been made. In essence, the instant case is no different than any of the other cases where this Court has struck down convictions because evidence was placed before the finder of fact that the defendant was not permitted to refute.

In *United States v. Nixon*, 418 U.S. 683, 709 (1974), this Court condemned in the strongest terms attempts to circumvent the adversarial process by asserting a privilege:

> We have elected to employ an adversary system of criminal justice in which the parties contest all issues before a court of law. The need to develop all relevant facts in the adversary system is both fundamental and comprehensive. The ends of criminal justice would be defeated if judgments were to be founded on a partial or speculative presentation of the facts.

The trial court's affirmative use of government documents reviewed *in camera* deprived Petitioners of the benefit of the adversary process.

And, the interpretation of the sixth amendment promoted by the Petitioners in this case has been adopted by the Sixth and Seventh Circuits. In *United States v. Douglas*, 155 F.2d 894

(7th Cir. 1946), the Seventh Circuit promptly reversed a conviction for violation of the Food, Drug, and Cosmetic Act on sixth amendment grounds where the trial judge submitted to the jury an affidavit by an individual not called as a witness at trial. The affidavit had been used to establish probable cause for the issuance of the criminal information. However, once the document was placed uncontested before the finder of fact, a "palpable infringement" of the defendant's sixth amendment confrontation rights resulted. *Accord. State v. Davidson*, 173 Mont. 510, 568 P.2d 159 (Sup. Ct. Mont. 1977) (nonadmitted police report obtained by jury); *State v. Albert*, 115 Ariz. 354, 565 P.2d 534 (Ariz. Ct. App. 1977) (introduction of search warrant and supporting affidavit of nonwitness).

In *Collins v. Buchkoe*, 493 F.2d 343 (6th Cir. 1974), the Sixth Circuit held that the trial judge erred in relying on a confidential document in sentencing a criminal defendant, where the defendant was not given the information contained in the document. The court stated that although it was permissible to consider this information in passing sentence, it was a violation of the defendant's right of confrontation to refuse the defendant the opportunity to contest the allegations contained in the documents. The decision of the Second Circuit in this case is patently in conflict with the decisions of the Sixth and Seventh Circuits in *Collins* and *Douglas*.

Petitioners' interpretation of the right of confrontation has also been accepted in the highest court of New York State. In *People v. Schainuck*, 286 N.Y. 161, 36 N.E.2d 94 (1941), the New York Court of Appeals, while not invoking the confrontation clause directly, held that the State could not elicit a defendant's admission that he had given inconsistent testimony in a prior administrative hearing without releasing to the defense a transcript of those hearings. The court held that the government could not assert that the contents of the transcripts were privileged and, at the same time, bring their substance into evidence at trial.

In *People v. Ramistella*, 306 N.Y. 379, 118 N.E.2d 566 (1954), the New York Court of Appeals added the weight of the sixth amendment to its reversal of a criminal conviction obtained after the State introduced evidence of a secret number stamped on an auto body frame to aid identification in theft cases. The trial judge refused to allow cross-examination regarding the location of this number because the state argued that revealing the location would hinder law enforcement. On the basis of *Coplon*, and this Court's opinion in *United States v. Reynolds*, 345 U.S. 1 (1953),[2] the New York Court of Appeals held that the sixth amendment prohibits the prosecution from using evidence withheld from the defendant to support a factual finding.

In sum, the prior decisions of this Court, and the decisions of both the New York state and lower federal courts lead inevitably to the conclusion that the sixth amendment right of confrontation prohibits the prosecution from using evidence, withheld from the defendant pursuant to a claim of privilege, to support an essential factual finding. Because the court of appeals has decided a question of constitutional law in a manner contrary to prior decisions of this Court and courts of appeals for the Sixth and Seventh Circuits, this Court should issue a writ of certiorari and review the decision below.

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2 In *Reynolds*, this Court noted that, "since the Government which prosecutes the accused also has the duty to see that justice is done, it is unconscionable to allow it to undertake prosecution and then invoke its governmental privileges to deprive the accused of anything which might be material to his defense." 345 U.S. at 12.

CONCLUSION

For the foregoing reasons, the writ of certiorari should be granted.

Dated: New York, New York
November 12, 1985

Respectfully submitted,

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APPENDIX

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 1455 — August Term, 1984

(Argued: July 15, 1985 Decided: September 13, 1985)

Docket No. 85-1037

UNITED STATES OF AMERICA,

Appellee,

—v.—

GEL SPICE COMPANY, INC. and BARRY ENGEL,

Defendants-Appellants.

Before:

PIERCE and PRATT, *Circuit Judges*, and STEWART, *District Judge.**

Appeal from orders and a judgment of the United States District Court for the Southern District of New York, McLaughlin, *Judge*, denying requests for discovery and for an evidentiary hearing on good faith, and convicting appellants of violating the Federal Food, Drug, and Cosmetic Act.

Affirmed.

* Honorable Charles E. Stewart, Jr., Senior District Judge, Southern District of New York, sitting by designation.

RAYMOND W. PHILLIPS, Office of Consumer Litigation, Civil Division, Department of Justice, Washington, D.C. (Richard K. Willard, Acting Assistant Attorney General, Raymond J. Dearie, United States Attorney, Thomas Roche, Assistant United States Attorney, Eastern District of New York, J. Patrick Glynn, Beverly Sherman Nash, Offiice of Consumer Litigation, Civil Division, Department of Justice, Washington, D.C., David G. Adams, Jeffrey Freedman, Associate Chief Counsel, Food and Drug Administration, Washington, D.C., of counsel), *for Appellee.*

J. DANIEL MAHONEY, New York, New York (Craig P. Murphy, Clifford G. Skibinsky, Windels, Marx, Davies & Ives, New York, N.Y., of counsel), *for Defendants-Appellants.*

PIERCE, *Circuit Judge:*

Gel Spice Company, Inc. (Gel Spice) and Barry Engel, President of Gel Spice, appeal from a judgment of the United States District Court for the Eastern District of New York (McLaughlin, *Judge*), dated December 21, 1984, which found appellants guilty, after a bench trial, on all ten counts of an information charging them with violating the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 342(a)(4).

The district court found that the government did not act in bad faith in conducting inspections of Gel Spice's facilities and that Gel Spice had not made a sufficient preliminary showing to warrant an evidentiary hearing on

this issue or to warrant access to certain government documents sought by appellants. The district court also held that appellant Engel did not establish the defense of impossibility. We affirm the decision of the district court.

BACKGROUND

At all relevant times, Gel Spice, a New York corporation, imported, processed, and packaged spices. The processing involved grinding, blowing, sifting, and repackaging the spices into consumer and industrial size containers. Barry Engel has been the President of Gel Spice since 1963 and has been responsible for the purchasing of spices and their storing, processing, andd packaging at the company's office and warehouse at 593 McDonald Avenue, Brooklyn, New York. He, his brother Andre S. Engel, Gel Spice's Vice-President, and their mother owned equal shares of Gel Spice and signed checks and documents on behalf of the company.

The Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 301 *et seq.*, is enforced by the Food and Drug Administration (FDA). The purpose of the Act is the protection of the public from foods that are exposed to unsanitary conditions. The statute requires that foods be produced and held in sanitary facilities. 21 U.S.C. § 342 (a)(4). It prohibits distribution of "adulterated" food, which is defined, in part, as food which may have become contaminated with filth, regardless of whether filth is actually found in the food itself. *Id.*

FDA's primary statutory tool to ensure compliance with the Act is the statutory inspection authority granted in 21 U.S.C. § 374. FDA officials and employees are authorized by this provision "to enter, at reasonable times, [after presenting appropriate credentials and a written

notice to the owner] any . . . establishment in which food [and other regulated products] are manufactured, processed, packed, or held . . . and . . . to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such . . . establishment, [including the facility's] equipment, finished and unfinished materials[,] containers, and labeling." 21 U.S.C. § 374(a)(1). Nothing in 21 U.S.C. § 374 requires FDA to obtain a warrant from a judicial officer.

The Act provides FDA with three principal enforcement mechanisms when it determines that the Act has been violated. The agency can request the United States Department of Justice (DOJ) to initiate a civil seizure action against any food that is adulterated, 21 U.S.C. § 334, seek an injunction to restrain violations of any prohibited act, 21 U.S.C. §§ 331 and 332, or seek to initiate criminal proceedings against any person who commits a prohibited act, 21 U.S.C. §§ 331 and 333.

According to the government, the customary manner in which a legal action is initiated by FDA is as follows:

1. An inspection is conducted by an FDA investigator and a report is prepared.

2. Where inspection reveals violative conditions, the inspection report is referred to the Compliance Branch of the field office for review.

3. The field office may then recommend appropriate regulatory action (including legal action), if any, to the pertinent FDA Bureau, in this case the Bureau of Foods.

4. Where the possible legal action is criminal prosecution, the field office provides the potential de-

fendants with an Opportunity to Present Views, pursuant to 21 U.S.C. § 335, and 21 CFR 7.84 *et seq.* (a Section 305 hearing). The record from the hearing is then reviewed by the field office in determining appropriate legal action, if any.

5. The field [office's] recommended course of action is reviewed by the Bureau. If the Bureau concurs in the recommendation, the matter is then referred for approval to [the] Enforcement Policy Staff.

6. Recommendations for regulatory action, if approved by [that] office, are referred to the Office of General Counsel of FDA for review and approval.

7. If approved by FDA's Chief Counsel, then, *and only then*, is a matter formally referred to Justice (through the appropriate U.S. Attorney) for the institution of legal proceedings.

Appellee's Brief at 7-8.

In June 1972, FDA inspected Gel Spice and found a widespread rodent infestation at the firm. When reinspected in August 1972, there was evidence of a continuing rodent infestation. According to the government, following the June and August 1972 inspections, FDA considered a criminal prosecution against Gel Spice. However, before deciding whether to refer the case to the DOJ, FDA's Chief Counsel requested another inspection to determine current conditions. As a consequence, there was a July 1973 reinspection at which no evidence of rodent infestation was found, and therefore no referral for criminal prosecution was made to the DOJ.

Three years later in July 1976, the FDA inspected Gel Spice and found active rodent infestation. A civil

seizure court action was instituted pursuant to 21 U.S.C. § 334 against Gel Spice's foods that were adulterated. In October 1976, FDA held a Section 305 hearing to determine if Gel Spice should be criminally prosecuted based upon the results of the July 1976 inspection. Section 305 hearings afford a person against whom the FDA is contemplating a criminal prosecution "appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding" before the matter is referred to the United States Attorney for prosecution. 21 U.S.C. § 335. Following the section 305 hearing during which Gel Spice presented its views, FDA's New York District Office, in February 1977, recommended to the Bureau of Foods that it consider the criminal prosecution of Gel Spice for the July 1976 inspection.

Another inspection of Gel Spice's premises occurred on March 30, 1977. According to the government, this inspection was conducted pursuant to the FDA New York District Office's March 1977 work plans which, based upon several factors, including the prior regulatory history of the firm and the particular commodity manufactured or processed and the risk it presents, identify for each investigator the establishments he is assigned to inspect. This inspection again showed the presence of adulterated food; the FDA initiated another civil seizure action and the District Office again recommended to the Bureau of Foods that Gel Spice be issued a Section 305 hearing notice of possible criminal prosecution arising out of the March 1977 inspection.

Prior to a decision on this request for a hearing, Gel Spice was inspected again on July 6, 1977, allegedly as a result of a report received by FDA's Philadelphia District Office from the United States Defense Personnel Supply Agency. The Supply Agency had received and rejected a

shipment of ground cinnamon manufactured by Gel Spice. The cinnamon had been rejected because of animal infestation. This July 1977 inspection revealed still more adulterated foods in Gel Spice's premises. Again, FDA initiated a civil seizure action as to the violative food products.

Thereafter, the District Office held a Section 305 hearing concerning both 1977 inspections. On February 28, 1978, FDA's New York Office submitted its prosecution recommendation based on the two 1977 inspections. The District Office's previous recommendation concerning the July 1976 inspection was still pending at the Bureau of Foods, so that after review of the charges arising out of the three inspections (July 1976, March 1977, and July 1977), on March 22, 1978 the Bureau approved and forwarded a prosecution recommendation to FDA's Enforcement Policy Staff headed by Joseph Hile. Hile approved and forwarded the recommendation to FDA's Chief Counsel. After final review, on September 18, 1978, the Chief Counsel referred the matter to the United States Attorney for the Eastern District of New York for prosecution. The referral covered violations disclosed during the July 1976 and March and July 1977 inspections. Subsequently, in January 1979, again consistent with its regular work plans, another inspection was made of Gel Spice which again revealed active rodent infestation. Following a civil seizure, a § 305 hearing, in which Gel Spice participated, and all the necessary reviews, on November 21, 1979, the FDA's Chief Counsel made a further recommendation to the United States Attorney for prosecution arising out of the January 1979 inspection. The government provided Gel Spice with copies of the inspection reports covering each one of these inspections, all of which were conducted without warrants pursuant to 21 U.S.C. § 374.

By information filed in the Eastern District of New York in December 1980, Gel Spice, Barry Engel, and Andre Engel were charged with causing various spices to become "adulterated", in that the spices were held under unsanitary conditions whereby they became contaminated with filth, within the meaning of 21 U.S.C. § 342(a)(4) (Counts I-X) or that some of the foods consisted in part of a filthy substance by reason of the presence of rodent infestation, within the meaning of 21 U.S.C. § 342(a)(3) (Counts I, II, III, and VIII). Proof of either charge establishes a violation of 21 U.S.C. § 331(k), which prohibits the doing of any act or the causing thereof, that results in food becoming adulterated while held for sale after shipment in interstate commerce. Gel Spice and Barry Engel were named in all ten counts, and Andre Engel was named in Counts I through VII. The charges in the information were based on evidence during the four inspections which took place in July 1976, March 1977, July 1977, and January 1979.

On April 9, 1981, Gel Spice filed a motion seeking to suppress evidence and dismiss the information. In support, Gel Spice filed an affidavit by its trial counsel, Jerold W. Dorfman, claiming that the government had obtained the evidence underlying the information in bad faith by using a civil administrative proceeding to obtain evidence for a criminal prosecution. Gel Spice alleged that the FDA had decided to prosecute it in March 1973, following the 1972 inspections, and had actually conducted the four subesquent inspections in question in order to gather evidence in support of that prosecution.

The case was assigned to Judge McLaughlin who, in April 1982, referred the motion to Magistrate Chrein for report and recommendation. Initially, Magistrate

Chrein held that Gel Spice had raised sufficient factual questions to require an evidentiary hearing on the issue of the government's bad faith, as Gel Spice had requested. The Magistrate also stated that he would review, in camera, internal FDA memoranda which the government refused to disclose to Gel Spice, citing the investigative records exception of Fed. R. Crim. P. 16(a)(2). In response to the bad faith claim, the government filed the declaration of Joseps Hile, FDA Associate Commissioner for Regulatory Affairs, dated May 15, 1982. The Hile declaration alleged that the "first formal institutional decision to prosecute" Gel Spice was made on September 18, 1978. Based upon this declaration and following an in camera inspection on June 29, 1982, of internal government documents of which discovery was sought by Gel Spice, the Magistrate changed his mind and concluded that he should not conduct an evidentiary hearing on the issue of the government's bad faith and should not disclose to Gel Spice the internal memoranda of FDA.

After defense counsel objected to the "Magistrate's findings on the ground that Gel Spice had been denied its sixth amendment right of confrontation because the Magistrate relied on documents it had not been allowed to see, the Magistrate asked the parties to submit briefs on the confrontation issue. On December 13, 1982, the Magistrate again changed his mind and entered an Interim Report and Recommendation calling for an evidentiary hearing to take place on January 4, 1983. The issues to be addressed at the hearing were the date upon which the government decided to prosecute Gel Spice and the government's alleged bad faith in pursuing the investigation of Gel Spice. Te Magistrate stated that an evidentiary hearing on the bad faith issue was necessary because the Hile declaration was ambiguous as to the reason

for a delay between the February 1977 prosecution recommendation by the FDA New York District Office and the September 1978 referral of the Gel Spice matter to the United States Attorney. Moreover, the Hile declaration was held to be ambiguous as to whether the February 1973 prosecution recommendation had been withdrawn or "placed in temporary abeyance," as alleged by appellants.

On December 28, 1982, the government submitted a document entitled "Government's Proffer of Alternative Modes for Showing that Inspections in Question Were Not Undertaken Solely for a Criminal, Evidence-Gathering Purpose." The government proffer contained two statements of FDA employees. A supplemental declaration of Joseph P. Hile asserted that the delay between the District Office recommendation to prosecute Gel Spice in 1977 and the 1978 referral of the matter to the United States Attorney was the result of normal administrative delay. A declaration of Frederick W. Blumenschein, a compliance officer with the FDA, asserted that the 1973 prosecution recommendation was, in fact, withdrawn during that year and not held in abeyance.

On January 4, the Magistrate again reversed himself and decided that Gel Spice was not entitled to a hearing on the issue of the FDA's bad faith since it had "failed to make a substantial preliminary showing of bad faith," sufficient to warrant an evidentiary hearing. In addition, based upon the government's proffer, the Magistrate concluded that September 1978 was the time of the "institutional decision to prosecute" and that inspections before that date were not conducted in bad faith. The district court adopted the Magistrate's Report and Recommendation.

Following a bench trial, on December 21, 1984, Judge McLaughlin found Gel Spice and Barry Engel guilty on all ten counts which charged violations of 21 U.S.C. § 342 (a)(4). In view of these findings, the court did not find it necessary to discuss the alleged violations of 21 U.S.C. § 342(a)(3). The court found Andre Engel not guilty on all counts in which he was charged. The Gel Spice corporate defendant was fined a total of $10,000. Barry Engel was sentenced to concurrent terms of two years probation on each count and fined a total of $10,000. This appeal followed.

Discussion

On appeal, Gel Spice contends that: (1) the FDA acted in bad faith by conducting four inspections, without warrants, pursuant to section 374 of the Act, after having already made a decision to prosecute Gel Spice; (2) Gel Spice was, at a minimum, entitled to an evidentiary hearing on the issue of bad faith; and (3) Gel Spice was improperly denied access to certain government documents. Barry Engel contends that the district court erred in concluding that he had not established the defense of impossibility. We find the arguments made on appeal to be without merit.

With regard to Gel Spice's contention of bad faith on the part of the FDA, we believe that, even when the FDA decides to utilize its criminal enforcement option pursuant to 21 U.S.C. §§ 331 and 333, it may not abandon its civil enforcement responsibilities and it is not thereby prohibited from any further agency surveillance under 21 U.S.C. § 374 pending the conclusion of criminal proceedings. If it were otherwise, anytime a prosecution was undertaken, the FDA would be precluded temporarily

in that particular instance from protecting the health and safety of the public, although this function constitutes the main purpose of the Act. As the Supreme Court stated in *United States* v. *Kordel*, 397 U.S. 1, 11 (1970):

> The public interest in protecting consumers throughout the Nation from misbranded drugs requires prompt action by the agency charged with responsibility for administration of the federal food and drug laws. But a rational decision whether to proceed criminally against those responsible for the misbranding may have to await consideration of a fuller record than that before the agency at the time of the civil seizure of the offending products. It would stultify enforcement of federal law to require a governmental agency such as the FDA invariably to choose either to forgo recommendation of a criminal prosecution once it seeks civil relief, or to defer civil proceedings pending the ultimate outcome of a criminal trial.

We therefore conclude that, even if the FDA were pursuing criminal enforcement of the Act at the time of the inspections in question, standing alone this does not imply or suggest that the inspections were conducted in bad faith.

Furthermore, in our view, Gel Spice's reliance on *United States* v. *LaSalie National Bank*, 437 U.S. 298 (1978) is misplaced. In *LaSalle*, the Supreme Court, relying on *Donaldson* v. *United States*, 400 U.S. 517 (1971), held that an Internal Revenue Service (IRS) subpoena is valid as long as it is issued in good-faith pursuit of congressionally authorized purposes and prior to any recommendation to the DOJ. *Id.* at 536. As the

government points out, the *LaSalle* Court's rationale for restricting the issuance of IRS subpoenas to the period before referral to the DOJ for criminal prosecution is based on its interpretation of the legislative intent behind Congress' grant of subpoena authority to the IRS, i.e., 26 U.S.C. § 7602. The same rationale is not applicable to the Food and Drug Act provisions at issue herein. For example, at the time of the *LaSalle* decision, 26 U.S.C. § 7602 granted the IRS the power to issue a summons for four purposes only: for "ascertaining the correctness of any return, making a return where none has been made, determining the liability of any person for any internal revenue tax or . . . collecting any such liability." In contrast, the FDA's food sanitation authority is a general grant "for purposes of enforcement of [the Act]," which Act authorizes criminal prosecution. Moreover, *LaSalle* has been distinguished in several other contexts, e.g., enforcement of subpoenas issued by the Securities and Exchange Commission, *SEC* v. *Dresser Industries, Inc.*, 628 F.2d 1368, 1377-84 (D.C. Cir.), *cert. denied*, 449 U.S. 993 (1980), by the Department of Energy, *United States* v. *Merit Petroleum Inc.*, 731 F.2d 901, 904-06 (TECA 1984), and by the Equal Employment Opportunity Commission, *In Re E.E.O.C.*, 709 F.2d 392, 398-99 (5th Cir. 1983). As the court noted in *United States* v. *Acklen*, 690 F.2d 70 (6th Cir. 1982), with regard to inspections by the Drug Enforcement Administration, *LaSalle* is inapplicable because that case "was decided on the basis of congressional intent behind 26 U.S.C. § 7602, not upon the consideration of the fourth amendment." *Id.* at 74 n.3. Based on the above, we conclude that the *LaSalle* rule is inapplicable herein.

Even if the Court were to apply the *LaSalle* rule to the FDA's inspections of Gel Spice, we believe that the

four inspections in question would be found to have been conducted in good faith, i.e., pursuant to a valid administrative scheme and not for the purpose of gathering evidence for a criminal prosecution. In *LaSalle*, the Supreme Court held that the critical time for determining whether a subpoena was issued in good faith is the time of the recommendation to the DOJ. Gel Spice contends that the FDA's consideration of criminal prosecution following the 1972 inspections is the critical time pursuant to *LaSalle*, and that all inspections subsequent to this time were conducted in bad faith, solely to accumulate evidence against them. We are unpersuaded by this argument.

First, after the reinspection in July 1973 which showed no infestation, no recommendation was made to the DOJ. The fact that the district office requested that its recommendation for prosecution be "placed in temporary abeyance" was explained by Blumenschein, in his declaration, to mean only that if further violations should occur sufficient to warrant a recommendation for prosecution, the prior violations could have been resubmitted provided the statute of limitations period had not run. In fact, however, the Bureau of Foods did not hold the matter in "temporary abeyance", but "disapproved the prosecution" of the 1972 violations and "suspended any action" on that prosecution.

Next, as the government notes, this prosecution concerns the July 1976 and subsequent inspections, which the FDA could not have decided to prosecute before the inspections were even made. Therefore, we agree with the district court that, at the time of the FDA inspections conducted in July 1976, March 1977, and July 1977, no institutional decision had been made by FDA to recommend criminal prosecution and that the institutional de-

cision to refer the matter to the DOJ for criminal prosecution did not occur until September 28, 1978. The only inspection that followed this decision was the January 1979 inspection and it is only this inspection for which the inquiry as to good faith is relevant.

As to whether the January 1979 inspection was conducted in good faith, as noted above, the mere existence of a pending recommendation for criminal prosecution to the DOJ does not mean that evidence obtained by the FDA during inspections conducted subsequent to the recommendation was improperly obtained. Civil and criminal enforcement may proceed simultaneously. *Kordel*, 397 U.S. at 11. Moreover, Magistrate Chrein found that the January 1979 inspection was in fact conducted in good faith, this finding was adopted by the district court and we believe it is supported by the record. The declarations of Hile and Blumenschein show that Gel Spice had a history of noncompliance and therefore that more frequent inspections were justified, and evidence was introduced at trial showing that the 1979 inspection was conducted pursuant to the District Office's work plan and not to further its prosecution recommendation. We therefore agree with the district court's conclusion that the Jaunary 1979 inspection was also conducted in good faith.

Gel Spice next contends that, at the least, an evidentiary hearing should have been held on the issue of bad faith, and that it should have been permitted access to the internal agency documents that the Magistrate reviewed in camera.

With regard to both the evidentiary hearing and discovery of the documents, we have held that the burden is on defendants to make a "substantial preliminary

showing" of bad faith before an evidentiary hearing or even limited discovery is to be held. *United States* v. *Tiffany Fine Arts, Inc.*, 718 F.2d 7, 14 (2d Cir. 1983), *aff'd*, 105 S. Ct. 725, 733 n.7 (1985); *United States* v. *Morgan Guaranty Trust Co.*, 572 F.2d 36, 42-43 n.9 (2d Cir.), *cert. denied*, 439 U.S. 822 (1978). We agree that Gel Spice failed to make a substantial preliminary showing of bad faith.

The only evidence presented to support its argument that the inspections were not conducted pursuant to a valid administrative scheme is the statement made in a summary inspection report and quoted in the affidavit of Jerold W. Dorfman, Gel Spice's counsel, that a decision to prosecute was made in 1973 and "was placed in temporary abeyance." As we have noted, this statement seems to have been adequately explained by the Blumenschein affidavit. Moreover, at no time in 1972 or 1973 was any referral actually made to the DOJ.

Furthermore, with regard to Gel Spice's demand to inspect the government documents, the government made no affirmative use of the privileged materials that were submitted in camera. Rather, the documents were submitted solely to rebut Gel Spice's claim that the government improperly obtained evidence in its inspections of Gel Spice. The government's evidence at trial arose from the four separate inspections, reports of which Gel Spice acknowledges it received. As the Supreme Court stated in *McCray* v. *Illinois*, 386 U.S. 300, 311 (1967), a compulsory disclosure rule is not applied "where the issue is the preliminary one of probable cause, and guilt or innocence is not at stake." Also, Fed. R. Crim. P. 16 (d) (1) permits an ex parte showing when a party seeks to prevent the inspection of documents that are alleged

to be confidential, and Fed. R. Crim. P. 12(i) permits a court to excise privileged matters from inspection by the defendants. Therefore, in our view, the district court did not abuse its discretion either in denying Gel Spice an evidentiary hearing on the issue of bad faith or in finding that Gel Spice was not entitled to discovery of internal FDA records related to the inspection of the Gel Spice premises beyond those already in their possession.

Finally, we conclude that the district court properly found that appellant Barry Engel failed to introduce sufficient evidence to establish the defense of impossibility. With regard to the impossibility defense, the district court stated:

> To establish the impossibility defense the corporate officer must introduce evidence that he exercised extraordinary care, but was nevertheless unable to prevent violations of the Act. The defense is raised when defendant introduces sufficient evidence of the exercise of extraordinary care to justify placing an additional burden on the government—that of proving beyond a reasonable doubt that had the defendant indeed exercised such extraordinary care, he could have prevented or corrected those violations. *United States* v. *New England Grocers Co.*, 488 F. Supp. [230,] 234 [D. Mass. 1980].

According to Engel, *New England Grocers Supply Co.* is not a correct statement of the impossibility defense. He argues that the impossibility defense does not require him to have exercised extraordinary care to prevent the violations of the Act, but rather requires only that he produce some evidence that he was powerless to prevent the contamination and filth. To support his position,

Engel relies on *United States* v. *Park*, 421 U.S. 658 (1975), in which the Supreme Court stated that "the Act imposes the highest standard of care and permits conviction of responsible corporate officials who, in light of this standard of care, have the power to prevent or correct violations of its provisions." *Id.* at 676.

Even if Engel's interpretation of *Park* were accurate, Engel has still failed to introduce any evidence that he was powerless to prevent the rodent infestation. Indeed, Gel Spice had passed an FDA inspection in 1972 and five other inspections between 1973 and the July 1976 inspection. Therefore, it was clearly possible for Engel to have prevented the infestation. Moreover, in *Park*, the Court stated that the defendant has "not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur." *Id.* at 672. Given the "shocking" amount of contamination found on the Gel Spice premises, we conclude that the district court did not err in finding that Gel Spice had failed to satisfy its duty pursuant to *Park* and that it had not established the defense of impossibility.

We therefore affirm the decision of the district court.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

December 21, 1984

No. 80 CR 650

UNITED STATES OF AMERICA,

—v.—

GEL SPICE CO., INC., Barry Engel and Andre S. Engel,

Defendants.

Defendants, a food importer, its president and vice-president, were charged with causing various articles of food that had been shipped in interstate commerce to be held for sale in a building accessible to rodents, thereby exposing the food to contamination of rodent filth, in violation of the Federal Food, Drug, and Cosmetic Act. The District Court, McLaughlin, J., held that: (1) evidence supported finding that company violated Act section by allowing food in its warehouse to become "adulterated"; (2) company's president who was principally responsible for plant sanitation was properly assigned guilt for his company's violations of the Act; and (3) president failed to present sufficient proof of impossibility defense to the charges.

Ordered accordingly.

See also D.C., 601 F.Supp. 1214.

U.S. Dept. of Justice, for the U.S.; Raymond W. Philipps, Beverly S. Nash, Washington, D.C., of counsel.

FRIEND, DORFMAN & MARKS, New York City, for defendants Gel Spice Co. and Barry Engel; Jerold W. Dorfman, New York City, of counsel.

PERLES & ALBERT, New York City, for defendant Andre S. Engel; David A. Beale, New York City, of counsel.

MEMORANDUM AND ORDER

MCLAUGHLIN, *District Judge*

This criminal prosecution under the Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. §§ 301 *et seq.*, was initiated with the filing of a ten-count Information on December 3, 1980. The information charges Gel Spice Co., Inc. ("Gel Spice"), its President, Barry Engel, and its Vice-President, Andre S. Engel, with causing various articles of food that had been shipped in interstate commerce to be held for sale in a building accessible to rodents, thereby exposing the food to contamination of rodent filth. This, it is charged, resulted in the food becoming adulterated (a) within the meaning of 21 U.S.C. § 342(a)(4) (1976),[1] in that various lots of food were held under insanitary conditions whereby they may have become contaminated with filth (all Counts); and (b) within the meaning of 21 U.S.C. § 342(a)(3) (1976),[2] in that the food consisted in part of a filthy substance by reason of the presence therein of rodent excreta pellets, rodent gnawings, rodent hair or rodent urine (Counts I, II, III and VIII). Proof of either

1. Subsection (a)(4) of 21 U.S.C. § 342 (1976) provides: "A food shall be deemed to be adulterated . . . (a)(4) if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health . . . ."

2. Subsection (a)(3) provides: "A food shall be deemed to be adulterated . . . (a)(3) if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food . . . ."

charge is a violation of 21 U.S.C. § 331(k) (1976),[3] which prohibits the doing of any act that results in food becoming adulterated while being held for sale after shipment in interstate commerce.

Each Count of this Information is predicated upon inspections by employees of the United States Food and Drug Administration ("FDA") of the McDonald Avenue, Brooklyn, N.Y., food warehouse operated by Gel Spice. Counts I and II arise from an FDA inspection in July 1976; Counts IV and V from an inspection in March 1977; Counts III, VI and VII from an inspection in July 1977; and Counts VIII, IX and X from an inspection in January 1979. The corporation and Barry Engel are named in all ten counts; Andre Engel is named in Counts I through VII.

After a lengthy period of discovery and motion practice,[4] a bench trial was held on February 29, March 1, 2 and 5, 1984. Extensive briefs and memoranda were subsequently filed. The following constitute the Court's findings of fact and conclusions of law. Fed.R.Crim.P. 23(c).

Findings of Fact

Gel Spice was incorporated under the laws of New York State in 1955. Since 1969 it has had an office and warehouse at 593 McDonald Avenue, Brooklyn, New York. Gel Spice imports, processes, and packages spices. The processing involves

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3. Subsection (k) of 21 U.S.C. § 331 provides: "The following acts and the causing thereof are hereby prohibited: . . . the doing of any . . . act with respect to, a food . . . if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated."

4. Defendants made several motions to suppress evidence and to dismiss certain counts of the Information. These were referred to the Magistrate for Report and Recommendation. 28 U.S.C. § 636(b). Magistrate Chrein of the Court submitted both an Interim and Final Report and Recommendation, copies of which are annexed to this Opinion. Defendants filed objections, and this Court ruled orally on them. A copy of the Memorandum and Order embodying that oral ruling is also annexed to this Opinion.

grinding, blowing, sifting, and repackaging the spices into consumer and industrial size containers.

Barry Engel has been the President of Gel Spice since 1963, and is responsible for the purchasing of spices and their storing, processing and packaging at the McDonald Avenue facility. His brother, Andre Engel, is responsible for sales. Their mother, Margaret Engel, handles the financial operation of the company. All have equal shares in Gel Spice and may sign checks and documents on behalf of the company.

The McDonald Avenue facility is 300′ × 125′ × 14′ and is divided into five separate areas: A large main raw materials storage room for receiving and storing spices; and adjacent production room for processing the spices, and next to that a packaging materials storage room. There are, in addition, an office area on the McDonald Avenue side of the production room and a cool room on the McDonald Avenue side of the packaging materials storage room. Two sliding garage doors open on to McDonald Avenue, one in the main storage room and the other in the packaging materials storage room.[5]

Gel Spice imports spices from abroad, particularly from South America, Europe and the Middle East. The spices are imported by ship and unloaded at piers. When the spices

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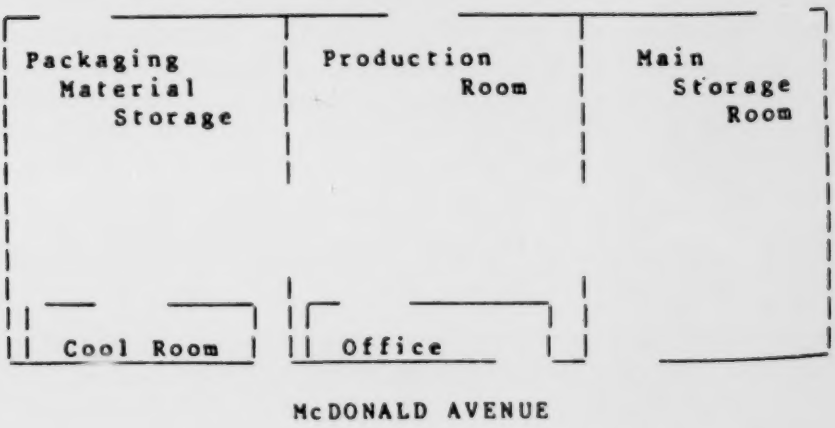
5. The warehouse is as appears below:



arrive, an official sampler from an outside firm is sent by Gel Spice to take a random sample from the bags.

The sampler follows procedures and standards published by the American Spice Trade Association and the sample is tested for Gel Spice by an independent laboratory using those standards. Gel Spice's decisions regarding the acceptance and use of the merchandise are based on the results of that test. It is notable that no examination is made at the pier of the outside of the bags, and only a random number of bags have samples drawn from within.

If the sampled spices pass the pier inspection, then the entire shipment is brought to the McDonald Avenue warehouse. Everyone in the trade knows that imported spices can arrive at the Gel Spice facility in a contaminated state; accordingly, measures must be taken to avoid bringing rodents into the building. When the spices arrive, a Gel Spice employee looks for evidence of rodent activity. Employees also scan the bags with a "black light" that will expose possible urine stains. At any given time, there may be 10,000 or more bags of spice stored at Gel's premises.

From 1976 through 1979 Gel Spice had an ongoing sanitation and rodent control program. The firm once used DDT before that insecticide was banned. DDT was quite efficient. The insecticide was spread around the doorways and around the plant and no mice would cross the DDT to come into the building. When DDT was banned, the company's exterminator recommended bait stations, traps, and then glue boards. Bait stations involve the use of poisoned food; traps catch the rodents.

Continuing their effort to develop an effective sanitation program, defendants retained various firms, all of whom promised satisfactory results. Between 1974 and 1979 Gel Spice had four different outside exterminators, who would come once each week or every two weeks. During this period, Gel Spice was inspected four times by the FDA. Those inspections form the basis of this Information.

A. *The July 1976 Inspection (Counts I, II)*

In July 1976 FDA Investigators Thomas Gardine and Brian Landesberg inspected the McDonald Avenue warehouse. They examined a lot of chili peppers in the warehouse's cool room. Inspector Gardine saw several dead rodents on bags of a different spice next to the lot of chili peppers. He also observed several dead rodents on the floor, one of which was covered with maggots and which, in Gardine's opinion, had been decomposing for at least one week. Throughout various areas of the cool room Inspector Gardine observed rodent excreta pellets. Burlap cuttings from the bags of chili pepper tested positively for mammalian urine, as did samples of the peppers themselves.

In the raw material storage room Inspector Gardine examined a lot of sesame seed, which forms the basis of Count II of the Information. He observed a decomposing rodent along the east wall of that room, and what appeared to be a rodent gnaw hole through one of the bags to the sesame seed. Burlap cuttings from various bags tested positively for mammalian urine, as did samples of the sesame seed. Several product samples also tested positively for rodent excreta.

On the other side of the warehouse, in the packaging materials storage room, Gardine observed several decomposing rodents, both in and out of bait boxes. Additionally, he saw numerous access holes for rodents throughout the warehouse.

B. *The March 1977 Inspection (Counts IV, V)*

Counts IV and V of the Information arise out of a March 1977 inspection of lots of marjoram and basil. Investigator Edward Miracco testified that the marjoram was in the main storage room. On the bags of marjoram, Miracco found rodent excreta pellets and numerous dead beetle-like insects. Sifting through the marjoram itself, Miracco found dead insects. Samples of marjoram later tested positively for rodent excreta pellets and red flour beetles.

Miracco also examined a lot of basil, finding rodent excreta pellets on six of the 34 bags he inspected. Burlap cuttings from

seven of the bags tested positively for mammalian urine. On the floor of the main storage room was spilled sodium bisulfate; Miracco saw rodent tracks through the chemical. He also saw a hole in a sliding door opening from the area adjacent to the cool room on to McDonald Avenue.

C. *The July 1977 Inspection (Counts III, VI, VII)*

Counts III, VI and VII arise respectively from a July 1977 FDA Inspection of lots of arrowroot flour, sesame seed and whole chili pepper. The arrowroot flour was in the main storage room. Investigator Bodner observed rodent pellets on and around the various bags. Rodent hairs were found around a gnaw hole in one bag, and 28 different cuttings tested positively for mammalian urine.

The sesame seed was stored in the cool room. Rodent pellets were scattered throughout the various bags of seed, and one pellet was lying on sesame seed in a torn bag. Eight samples of burlap bag cuttings tested positively for mammalian urine, and thirteen samples of the sesame seed itself tested positively for rodent pellets. Also stored in the cool room was a lot of whole chili pepper. There were many rodent excreta pellets on and around the bags.

In the course of this inspection, Investigators Bodner and Lesser observed other signs of rodent activity throughout the plant: live rodents; a dead rodent; and rodent excreta pellets. Four bait boxes had no bait in them and the hole in the sliding door to McDonald Avenue, first noticed by Investigator Miracco in the March 1977 inspection, still had not been closed.

D. *The January 1979 Inspection (Counts VIII, IX, X)*

The final FDA Inspection of Gel Spice's warehouse occurred in January 1979. Examinations of lots of basil, aniseed and bay leaves led to Counts VIII, IX and X of the Information.

Investigator Richard Pecora inspected a lot of basil, which was stored in the main storage room. He observed more than 300 rodent pellets on the bags and surrounding floor. He also

observed, and photographed, four live rodents nesting inside one of the bags of basil. From that bag he extracted a sample of basil, which was found to contain rodent hair and excreta as well as nesting material.

Also located in the main storage room was the aniseed involved in Count IX. Pecora counted over 200 rodent excreta pellets on and around the bags of aniseed. He found the remnants of a rodent's nest in one of the bags, as well as a roll of toilet paper, which appeared to have been gnawed by a rodent, on the floor next to the bag.

Finally, Pecora inspected a lot of bay leaves, which was stored approximately 30 feet from the aniseed. He discovered rodent excreta pellets on the bags, and a 7.6 ounce sample of bay leaf contained two more rodent pellets. A general inspection of the entire warehouse revealed more rodent pellets, a decomposed rodent in the cool room, and open drums of spices as well as spilled spices.

Conclusions of Law

The information charges ten violations of 21 U.S.C. § 331(k). These charges may be proven by showing the following: (1) the articles involved in the Information were food; (2) they were held for sale by Gel Spice after shipment in interstate commerce; and (3) the articles were adulterated within the meaning of either 21 U.S.C. § 342(a)(3) or § (a)(4). There is no dispute regarding the first two elements of the offense. The case, therefore, turns on whether the government has proven the third element beyond a reasonable doubt. There is also a question as to the applicability of certain defenses.

A. *Corporate Liability*

All ten counts of the Information charge Gel Spice Co. with violating 21 U.S.C. § 342(a)(4), which states that food shall be deemed adulterated "if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." To prove a violation of this subsection,

the government need only prove that the food was held under insanitary conditions, creating a reasonable possibility of contamination; proof of actual contamination is not required. *See United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 90-91, 84 S.Ct. 559, 562-563, 11 L.Ed.2d 536 (1964); *accord Berger v. United States*, 200 F.2d 818, 821 (8th Cir. 1952). Proof of actual contamination is, however, evidence that the food has been held under insanitary conditions. *Id.* at 823. Moreover, when insanitary conditions are adjacent to food there exists a reasonable possibility that the food may become contaminated. *United States v. Cassaro, Inc.*, 443 F.2d 153, 157 (1st Cir. 1971).

Filth, as that term is used in §§ 342(a)(3) and § 342(a)(4), is given its common meaning. *United States v. Cassaro, Inc.*, *supra*, 443 F.2d at 156. It is defined as "foul matter; offensive or disgusting." Random House, Inc., *Dictionary of the English Language Unabridged* 53 (1966). Thus, food is adulterated within the meaning of § 342(a)(4) when it is stored in conditions creating a reasonable possibility that it may become contaminated with foul, offensive or disgusting mattter.

Applying this standard, the evidence that Gel Spice violated § 342(a)(4) is overwhelming. The testimony of the F.D.A. investigators, corroborated by the results of laboratory analyses and by graphic photographs, proves beyond a reasonable doubt that Gel Spice held food for sale after it had been shipped in interstate commerce, under conditions whereby it may have become adulterated with filth. Accordingly, I find the corporate defendant, Gel Spice Co., guilty of ten counts of violating § 331(k), by violating § 342(a)(4).[6]

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6. Because the evidence clearly establishes violations of § 331(k) flowing from violations of § 342(a)(4), there is no need to make any findings regarding defendants' guilt based on violations of § 342(a)(3). Proof of the § 342(a)(4) violation alone is sufficient to establish a violation of § 331(k).

B. *Individual Liability*

Defendant Barry Engel, President of Gel Spice Co., is named in all ten counts of the Information. His brother, Andre Engel, is Vice President of Gel Spice Co. and is named in Counts I through VII of the Information. For the reasons developed below, I find Barry Engel guilty and Andre Engel not guilty of all counts charged against them.

Under the Act, individual culpability for criminal acts of a business attaches to any person who exercises responsibility in the conduct of the business, whether or not the individual intended to violate the law or knew of the violative acts. All the government must prove is that the individual was in a position of power or authority to prevent, detect or correct violations of the Act. *United States v. Park*, 421 U.S. 658, 670-71, 95 S.Ct. 1903, 1910-11, 44 L.Ed.2d 489 (1975); *United States v. Dotterweich*, 320 U.S. 277, 284-85, 64 S.Ct. 134, 138-39, 88 L.Ed. 48 (1943); *United States v. Torigian Laboratories*, 577 F.Supp. 1514, 1529 (E.D.N.Y), *aff'd mem.*, 751 F.2d 373 (2d Cir. 1984).

The Act "dispenses with the need to prove 'consciousness of wrongdoing.' " *United States v. Park*, *supra*, 421 U.S. at 669, 95 S.Ct. at 1910. As the Supreme Court stated in *Park*:

> [I]n providing sanctions which reach and touch the individuals who execute the corporate mission . . . the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur.
>
> * * * * *
>
> [T]he Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so. The failure thus to fulfill the duty imposed by the

> interaction of the corporate agent's authority and the statute furnishes a sufficient causal link. The considerations which prompted the imposition of this duty, and the scope of the duty, provide the measure of culpability.

Id. at 672-74, 95 S.Ct. at 1911-13. (citations omitted).

The government's proof at trial demonstrated beyond a reasonable doubt that Barry Engel was in a position of authority in the corporation to prevent or correct violations of the Act and that he did not do so. He was not "powerless to prevent or correct the violation[s]." *Id.* at 673, 95 S.Ct. at 1912.

Barry Engel testified that he was principally responsible for plant sanitation. He also admitted this to Investigator Gardine. Although there was testimony that day-to-day plant management is delegated to Mr. Jonas Grunzweig, the evidence is clear that Mr. Grunzweig reported to Barry Engel, that Barry Engel decided what methods of sanitation were to be used, and that Barry Engel controlled the hiring and firing of outside exterminators. Barry Engel was in a position of responsibility and authority to control the insanitary conditions at Gel Spice Co. *United States v. Park*, *supra*, 421 U.S. at 670-71, 95 S.Ct. at 1910-11. He is guilty of violating 21 U.S.C. § 331(k), as charged in all ten counts of the Information, because he did not exercise his responsibility and authority to control violations of § 342(a)(4) at the Gel Spice plant.

The government has not proved beyond a reasonable doubt that Andre Engel had the requisite responsibility and authority to warrant a finding of guilt against him. The government makes much of Andre Engel's position as Vice President, and the fact that he was present at the warehouse during the three inspections on which the Counts against him are predicated. Guilt may not be assigned, however, solely by virtue of a defendant's corporate position. *United States v. New England Grocers Supply Co.*, 488 F.Supp. 230, 232 (D.Mass. 1980) (citing *United States v. Park*, *supra*). Moreover, while Andre Engel was indeed present during three inspections, the FDA investigators were repeatedly told that he was filling in for

Barry Engel, that Andre's primary responsibility was sales, and that Barry was the person in charge of plant operation and sanitation. There is more than a resonable doubt that Andre Engel had responsibility and authority to control sanitary conditions at Gel Spice Co. Accordingly, I find Andre Engel not guilty of the charges contained against him in Counts I through VII.

C. *The Impossibility Defense*

Defendants contend that even if conditions at the warehouse were insanitary within the meaning of the Act, those conditions were impossible to prevent, and thus defendants are not guilty of violating § 342(a)(4). I find that defendants have not established the defense of impossibility.

The impossibility defense derives from the Supreme Court's discussion in *United States v. Park*, 421 U.S. 658, 95 S.Ct. 1903, 44 L.Ed.2d 489 (1975), of the criminal liability of corporate agents for violations of the Act:

> The duty imposed by Congress on responsible corporate agents is, we emphasize, one that requires the highest standard of foresight and vigilance, but the Act, in its criminal aspect, does not require that which is objectively impossible. The theory upon which responsible corporate agents are held criminally accountable for "causing" violations of the Act permits a claim that a defendant was "powerless" to prevent or correct the violation to "be raised defensively at a trial on the merits." *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91, 84 S.Ct. 559, 563, 11 L.Ed.2d 536 (1964).

Id. at 673, 95 S.Ct. at 1912.

Courts interpreting *Park* have assumed, without deciding, that the impossibility defense is available only to individuals. *See United States v. Starr*, 535 F.2d 512, 515-16 (9th Cir. 1976); *United States v. New England Grocers Supply Co.*, *supra*, 488 F.Supp. at 236. The context of the Supreme Court's discussion in *Park*, and the reference to the Court's earlier decision in

United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 91, 84 S.Ct. 559, 563, 11 L.Ed.2d 536 (1964) lead me to conclude that the impossibility defense is not available to a corporation. While the defense is available to Barry Engel, I find that he has not offered sufficient evidence to make it a genuine issue in this case and that, therefore, is it not a defense to Barry Engel or, a fortiori, to the corporation (assuming it were available to the latter).

To establish the impossibility defense the corporate officer must introduce evidence that he exercised extraordinary care, but was nevertheless unable to prevent violations of the Act. The defense is raised when defendant introduces sufficient evidence of the exercise of extraordinary care to justify placing an additional burden on the government—that of proving beyond a reasonable doubt that had defendant indeed exercised such extraordinary care, he could have prevented or corrected those violations. *United States v. New England Grocers Supply Co., supra*, 488 F.Supp. at 234; *see United States v. Wiesenfeld Warehouse Co., supra*, 376 U.S. at 91, 84 S.Ct. at 563.

The evidence is clear that, notwithstanding Barry Engel's protestations to the contrary, he did not exercise "extraordinary care" in administering Gel Spice's sanitation program. The shocking amount of rodent filth observed during the four inspections, including live maggots, the remains of dead rodents, and rodent nesting material belies any claim that the exercise of extraordinary care would not have resulted in the removal of much of this filth.[7] Additionally, the FDA investigators observed untended bait boxes, and numerous rodent access holes throughout the plant, such as broken windows, cracks in walls, and a hole in the sliding door opening on to McDonald Avenue. Barry Engel, President of Gel Spice and responsible for its sanitation program, was clearly not "power-

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7. Defendants assail the government for not introducing evidence of what other steps defendants should have taken to insure compliance with the Act. Defendants overlook, however, that impossibility is an affirmative defense, and that the burden of producing evidence of extraordinary care rests on defendants.

less to protect against this kind of contamination." *United States v. Wiesenfeld Warehouse Co., supra*, 376 U.S. at 91, 84 S.Ct. at 563.

Although defendants did introduce evidence of an ongoing rodent control program, that program did not constitute the extraordinary care required to establish the impossibility defense. Defendants passed an FDA inspection in 1972, and there is no evidence that the spice trade or the conditions surrounding the Gel Spice warehouse changed so much after 1972 that it became impossible for them to control rodent activity inside the warehouse. Indeed, defendants' own pictures of the warehouse, taken shortly before trial and introduced as exhibits (DX A101-A200), portray the warehouse as far cleaner than when it was inspected by the FDA between 1976 and 1979. Because defendants did not raise a genuine issue of impossibility, no additional burden was placed on the government.[8]

For the foregoing reasons, I find defendants Gel Spice Company and Barry Engel guilty of all ten Counts of the Information, which charged them with violating 21 U.S.C. § 331(k) in that they held food that had been shipped in interstate commerce for sale, in an adulterated condition as defined in 21 U.S.C. § 342(a)(4). I find defendant Andre Engel not guilty of violating 21 U.S.C. § 331(k). Because of my finding that defendants violated § 331(k) by violating § 342(a)(4), I need not discuss violations of § 342(a)(3).

Defendants shall report forthwith to the Probation Department. Sentencing shall take place at 10:00 a.m., February 8, 1985. At that time the Court will rule on the government's request to tax the full costs of this prosecution against defendants. 28 U.S.C. §§ 1918(b), 1920. The government is directed to furnish the Court and defendants with an itemization of the requested costs not later than January 18, 1985.

SO ORDERED.

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8. Because of my finding that defendants' guilt flows from violations of § 342(a)(4), there is no need to discuss the *de minimis* defense urged by defendants. That defense, if available at all, applies to charges of actual adulteration under § 342(a)(3). *See United States v. Certified Grocers Co-op*, 546 F.2d 1308, 1312 (7th Cir. 1976); *United States v. Capital City Foods*, 345 F.Supp. 277, 278 (D.N.D. 1972).

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

January 28, 1985

No. 80 CR 650

UNITED STATES OF AMERICA,

—v.—

GEL SPICE CO., INC.,
BARRY ENGEL AND ANDRE S. ENGEL,

Defendants.

Spice corporation, its president and its vice-president, were charged in ten-count information alleging, in substance, that they permitted food to become adulterated within meaning of Federal Food, Drug and Cosmetic Act. Defendants made several motions to suppress evidence and to dismiss certain counts of information. After Report and Recommendation of Magistrate A. Simon Chrein, the District Court, McLaughlin, J., held that: (1) FDA conducted its investigation pursuant to valid administrative scheme; (2) defendants were not entitled to discovery of internal FDA records related to inspection of defendants' premises; (3) ex parte examination of FDA documents was proper; (4) statements made by individual defendants were not subject to suppression; (5) records regarding shipment and importation of food would not be suppressed; (6) photographs of premises taken during inspections were lawfully obtained; and (7) dismissal of some counts of indictment was not warranted.

Order accordingly.

U.S. Dept. of Justice, Raymond W. Philipps, Beverly S. Nash, Washington, D.C., of counsel, for the U.S.

FRIEND, DORFMAN & MARKS, New York City (Jerold W. Dorfman, New York City, of counsel), for Gel Spice Co. and Barry Engel.

PERLES & ALBERT, New York City (David A. Beale, New York City, of counsel) for Andre S. Engel.

MEMORANDUM AND ORDER

MCLAUGHLIN, *District Judge*

The defendant corporation, its president, Barry Engel, and its vice-president, Andre Engel, are charged in a ten-count Information alleging, in substance, that the defendants permitted food to become adulterated within the meaning of §§ 342(a)(3) and 342(a)(4) of the Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.* Defendants made several motions to suppress evidence and to dismiss certain counts of the Information. United States Magistrate A. Simon Chrein of this Court denied those motions, and defendants have appealed. 28 U.S.C. § 636(b). This Memorandum and Order embodies ruling made orally on October 21, 1983.

Facts

Gel Spice, Inc. has been the subject of regular inspections by the Food and Drug Administration (FDA) since 1972. In July 1976, March-April 1977, and July 1977, FDA inspectors conducted three extensive inspections of the Gel Spice warehouse in Brooklyn, New York. On those occasions photographs were taken and certain lots of allegedly adulterated foods were seized.

Three hearings were subsequently held pursuant to § 305 of the Act, 21 U.S.C. § 335. Section 305 hearings afford a person

against whom the FDA is contemplating a criminal prosecution "appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding" before the matter is referred to the United States Attorney for prosecution. *Id.*

The first § 305 hearing was held on October 27, 1976 following the July 1976 inspection, and the second on December 20, 1977 following the March-April and July 1977 inspections. On September 18, 1978, the FDA Chief Counsel formally referred a request for prosecution of Gel Spice to the Office of the United States Attorney in the United States Department of Justice.

In January 1979, the FDA conducted another inspection, which disclosed an active rodent infestation on the Gel Spice premises. Another § 305 hearing was held on May 30, 1979; and this Information was filed in December 1980.

Discussion

1. *FDA's Good Faith*

Defendants' first motion is to dismiss the Information or to suppress evidence on the ground that the government obtained the evidence in bad faith; that is, that the government conducted the searches, not in furtherance of administrative purposes, but rather to obtain evidence for a criminal prosecution that was already planned. Defendants contend that they are entitled to an evidentiary hearing at least on the issue of the government's good faith.

A regulatory agency may investigate possible violations of law through its administrative process, provided that its inquiries are for a proper purpose, the information sought is relevant to that purpose, and the statutory procedures are observed. *United States v. Powell*, 379 U.S. 48, 57-58, 85 S.Ct. 248, 254-255, 13 L.Ed.2d 112 (1964). Once the agency has established the existence of a valid civil purpose, the burden shifts to the defendants to come forward with evidence of bad faith. *See United States v. O'Henry's Film Works*, 598 F.2d 313, 320 (2d Cir. 1979); *United States v. Morgan Guaranty*

Trust Co., 572 F.2d 36, 42-43 n. 9 (2d Cir.), *cert. denied*, 439 U.S. 822, 99 S.Ct. 89, 58 L.Ed.2d 114 (1978). Magistrate Chrein held (Interim Report and Recommendation at 11-12), and I agree, that the burden is on the defendants in this case "to disprove the actual existence of a valid . . . purpose . . ." *United States v. LaSalle National Bank*, 437 U.S. 298, 316, 98 S.Ct. 2357, 2367, 57 L.Ed.2d 221 (1978).

Before obtaining evidentiary hearing on the issue of the government's good faith, defendants must make a substantial preliminary showing of bad faith. *United States v. O'Henry's Film Works, supra*, 598 F.2d at 320; *United States v. Morgan Guaranty Trust Co., supra*, 572 F.2d at 42-43 n. 9; *United States v. Morgan Guaranty Trust Co.*, 524 F.Supp. 24, 27 (S.D.N.Y. 1981). To establish bad faith, defendants must show that the sole purpose of the investigation was investigatory, rather than regulatory. *United States v. LaSalle National Bank, supra*, 437 U.S. at 316-17, 98 S.Ct. at 2367-68; *Securities and Exchange Commission v. Dresser Industries, Inc.*, 628 F.2d 1368, 1387 (D.C. Cir.) (en banc), *cert. denied*, 449 U.S. 993, 101 S.Ct. 529, 66 L.Ed.2d 289 (1980); *United States v. Schutterle*, 586 F.2d 1201, 1203 (8th Cir. 1978).

I agree with Magistrate Chrein that the FDA conducted its investigation pursuant to a valid administrative scheme and not for the purpose of gathering evidence (Final Report and Recommendation at 2-3). Magistrate Chrein further found that the government made its decision on September 18, 1978, to prosecute defendants for the violations discovered at the July 1976, March-April 1977, and July 1977 inspections. The decision to prosecute defendants for the January 1979 violations was made on November 21, 1979. *Id.* These findings, which I adopt, undermine defendants' contention that the FDA inspections were "for an investigatory rather than regulatory purpose." *United States v. Shaefer, Michael and Clairton Slag, Inc.*, 637 F.2d 200, 204 (3d Cir. 1980).

An evidentiary hearing is not required without a meaningful factual showing of an improper purpose by the agency. *Securities and Exchange Commission v. Howatt*, 525 F.2d 226, 229

(1st Cir. 1975). I am satisfied that the defendants have made no such showing in this case. Accordingly, defendants' motion for dismissal, suppression or an evidentiary hearing regarding the good faith of the FDA is denied.

2. *Discovery of FDA Records*

Because I have found that defendants failed to make a substantial preliminary showing of bad faith, it follows that they are not entitled to discovery of internal FDA records related to the inspection of the Gel Spice premises beyond those already in their possession. I reject defendants' contention that they are entitled to discovery as a matter of law. In accordance with *United States v. Berrios*, 501 F.2d 1207 (2d Cir. 1974), Magistrate Chrein made an *in camera* inspection of the materials sought by defendants. He determined that the documents sought were not relevant to the defenses raised; that is, they would not tend to establish the elements of any defense (Interim Report and Recommendation at 16-17). Under *Berrios*, therefore, they need not be produced. I have conducted a *de novo* examination of the documents and conclude that they are not demonstrably relevant to the defenses raised. Furthermore, the documents in question closely parallel records that have already been provided to the defendants in discovery proceedings. Their right of confrontation has been rejected.

I am satisfied that Magistrate Chrein's *ex parte* examination of the documents was proper. Fed.R.Crim.P. 16(d)(1) permits a party to make an *ex parte* showing when seeking a protective order; the adversary's rights are protected by the fact that the text of the party's statement must be preserved in the event of an appeal. *Id.* Counsel for the government was present solely to identify documents and answer questions. The *ex parte* examination was well within the bounds of the Code of Professional Responsibility and the Code of Judicial Conduct. No prejudice has inured to defendants.

3. *Statements Made During FDA Inspections*

Defendants also move to suppress all statements made by Barry Engel and Andre Engel during the four inspections of the Gel Spice premises. The motions are based on alleged violations of defendants' rights under the Fourth and Fifth Amendments.

Defendants made the statements in question during inspections conducted pursuant to lawful authority and consistent with the requirements of the Act, 21 U.S.C. § 374. FDA personnel presented written notice of each inspection and produced the proper credentials. I agree with Magistrate Chrein that defendants consented to each of the inspections (Final Report and Recommendation at 11). Defendants have submitted no evidence to support their contention that statements were obtained from them involuntarily, either through coercion or duplicity. Because the defendants were not in custody, *Miranda* warnings were not required. *See United States v. Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532, 543 (8th Cir. 1981), *cert. denied*, 455 U.S. 1016, 102 S.Ct. 1709, 72 L.Ed.2d 133 (1982); *United States v. Dudgeon*, 279 F.Supp. 300, 302 (D.Mass. 1967). The statements were made voluntarily during lawful inspections; I therefore deny the motion to suppress.

4. *Statements Made at Section 305 Hearings*

Defendants have also moved to suppress statements made at the § 305 hearings. These hearings were held following the FDA inspections to give defendants an opportunity to head off a criminal prosecution for violation of the Act. *See* 21 U.S.C. § 335; 21 C.F.R. § 7.84 (1982). Defendants' motion to suppress is based on the allegation that at the time of each hearing the FDA had already recommended prosecution for the alleged violations that gave rise to the hearing. They contend that if statements made at such a hearing are not given adequate consideration before a decision to prosecute is reached, the maker of the statement has been misled as to the purpose of the hearing.

As noted above, however, I have adopted Magistrate Chrein's findings that the decision to prosecute was made after those hearings (Final Report and Recommendation at 2-3). Thus defendants have not been misled. I adopt Magistrate Chrein's finding that defendants were well aware of the possible consequences of the hearings (Final Report and Recommendation at 13); the notice of hearing makes clear that "any civil action which may have been taken against the goods involved, such as seizure, does not preclude prosecution of those responsible for the violation; *the hearing concerns the possible criminal action only.*" Accordingly, defendants' motion to suppress statements made during the § 305 hearings is denied.

5. *Suppression of Gel Spice Records*

The individual defendants have also moved under 21 U.S.C. § 373 to suppress records regarding the shipment and importation of certain foods. Section 373 provides that carriers engaged in interstate commerce and persons receiving food in interstate commerce or holding such articles so received must furnish to the FDA records relating to the shipment of foods. Section 373 states, however, that evidence obtained in this fashion "shall not be used in a criminal prosecution of the person from whom obtained." *Id.*

Immunity under § 373 arises when (1) the FDA has requested the records, (2) the custodian has refused to provide them, and (3) the FDA investigator again requests the records specifically under the authority of 21 U.S.C. § 373 and presents a written statement to that effect. *United States v. Lyon Drug Co.*, 122 F.Supp. 597, 601 (E.D. Wisc. 1954); *United States v. Scientific Aids Co.*, 117 F.Supp. 588, 589 (D.N.J. 1954). Magistrate Chrein found that the FDA investigators did not invoke the authority of § 373 to obtain the records, and, accordingly that the immunity provisions of the statute did not apply (Final Report and Recommendation at 3). Magistrate Chrein further found that defendants showed the records to the FDA investigators voluntarily, which also precludes invoca-

tion of § 373 immunity (Final Report and Recommendation at 4). *See United States v. Herold*, 136 F.Supp. 15, 16 (E.D.N.Y. 1955); *United States v. Lyon Drug Co.*, 122 F.Supp. at 599-601. I adopt Magistrate Chrein's findings on these issues and therefore, deny defendants' motion to suppress.

6. *Subpoena of Gel Spice Records*

Defendants have also moved to quash the trial subpoena of the same Gel Spice corporate records discussed in part 5, *supra*. Fed.R.Crim.P. 17(c) provides for the subpoena of corporate records, and, as a corporate defendant, Gel Spice is not entitled to claim Fifth Amendment protection against self-incrimination. *Wilson v. United States*, 221 U.S. 361, 382-84, 31 S.Ct. 538, 545-46, 55 L.Ed. 771 (1911); Wright, *Federal Practice and Procedure* § 274 (2d ed. 1982). Similarly, corporate officers enjoy no personal Fifth Amendment privilege with regard to corporate records even when those records might incriminate them personally. *Bellis v. United States*, 417 U.S. 85, 88-90, 94 S.Ct. 2179, 2182-2184, 40 L.Ed.2d 678 (1974). For these and the other reasons set forth in Magistrate Chrein's Final Report and Recommendation (at 4-11), the motion to quash the trial subpoena of Gel Spice records is denied.

7. *Photographs of Premises*

Defendants next contend that photographs of Gel Spice premises taken during the FDA inspections must be suppressed. They argue that the photographs were unlawfully obtained and are unfairly prejudicial.

The photographs were taken during lawful inspections conducted pursuant to 21 U.S.C. § 374 (1976). FDA personnel followed all applicable procedural requirements. There is no evidence of unlawfulness.

I also find no merit in defendants' contention that the photographs are unfairly prejudicial. The standard for admissibility is whether the photos fairly and accurately depict the scene. Magistrate Chrein found that there is no evidence that the photographs contain distortions (Interim Report and Rec-

ommendation at 5). In addition, before the photographs can be admitted at trial, a proper foundation for their admission must be laid. Defendants will be amply protected by their opportunity to cross-examine the FDA investigator through whom the photographs are offered.

Rule 403 of the Federal Rules of Evidence allows suppression if the probative value of the evidence is outweighed by the danger of unfair prejudice. Of course, relevant evidence is by its very nature prejudicial. The test is whether it is *unfairly* prejudicial. No basis exists for such a finding at the time. Accordingly, the motion to suppress the photographs is denied.

8. *Number of Counts in the Information*

Defendants' final objection is that because the charges in the Information are based on four investigations of the Gel Spice premises, the Information should contain no more than four counts. In their view only one crime may arise from one investigation. The government contends that there are as many crimes as there are different kinds of adultered foods.

Neither the Supreme Court nor the Second Circuit has spoken directly on this issue. A district court in this Circuit, however, has held that one unsanitary condition may support multiple convictions based on different foods. *United States v. J. Treffiletti & Sons*, 496 F.Supp. 53, 56 (N.D.N.Y. 1980); *see United States v. H.B. Gregory Co.*, 502 F.2d 700 (7th Cir. 1974), *cert. denied*, 422 U.S. 1007, 95 S.Ct. 2629, 45 L.Ed.2d 670 (1975); *Akin Distributors v. United States*, 399 F.2d 306, 307 (5th Cir. 1968), *cert. denied*, 394 U.S. 905, 89 S.Ct. 1013, 22 L.Ed.2d 216 (1969).

The applicable test for whether two violations constitute different offenses is whether each violation requires proof of an additional fact that the other does not. *Blockburger v. United States*, 284 U.S. 299, 304, 52 S.Ct. 180, 182, 76 L.Ed. 306 (1932). The ten counts in this Information involve different foods, manufactured in different countries, labeled differently, and shipped to defendants on different dates.

I agree with Magistrate Chrein that each count will require proof of additional facts (Interim Report and Recommendation at 7). Accordingly, defendants' motion to dismiss some of the counts in the Information is denied.

I have reviewed the record in this case and the Interim and Final Reports of Magistrate Chrein, and hereby adopt in full the findings contained therein.

SO ORDERED.

REPORT AND RECOMMENDATION OF UNITED STATES MAGISTRATE

July 15, 1983

A. SIMON CHREIN, *United States Magistrate.*

This report incorporates the findings and recommendations made in the interim report ("Report") submitted by the undersigned on December 13, 1982, a copy of which is attached. Although findings and recommendations were made with respect to seven matters in the interim report, defendants still had pending various motions to dismiss this prosecution and to suppress evidence after the report was filed. Decision on those motions was reserved pending testimony by the parties at evidentiary hearings which were held on January 4, 19 and 20, 1983. Having reviewed all of the papers submitted to date and having heard argument of all counsel on January 4th and the testimony of various witnesses on January 19th and 20th, I make the following findings and recommendations:

1. Concerning defendants' motion to dismiss or suppress evidence on the ground that the government obtained evidence in bad faith, i.e., inspections were conducted to gather evidence for a pre-determined criminal prosecution,[1] I recommend that defendants' motion be denied. Initially this question was reserved pending findings to be made at an evidentiary hearing.[2] However, after consideration of the documents submitted by the government in late December of 1982,[3] the undersigned finds that since defendants have failed to make a

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1. *See* item 5 of the December 13, 1982 report ("Report") at 9-14.

2. *See* Report at 11.

3. These documents include the following: Government's Proffer of Alternative Modes for Showing That Inspections in Question Were Not Undertaken Solely for a Criminal, Evidence Gathering Purpose dated December 28, 1982; Supplemental Declarations of Joseph P. Hile dated December 28, 1982; and Declaration of Frederick W. Blumenschein dated December 29, 1982.

substantial preliminary showing of bad faith, the defendants have not met their burden and, therefore, are not entitled to a hearing on the issue of the government's bad faith. *See United States v. O'Henry's Film Works*, 598 F.2d 313, 320 (2d Cir. 1979); *United States v. Morgan Guaranty Trust Company*, 572 F.2d 36, 43 n. 9 (2d Cir.), *cert. denied sub nom. Keech v. United States*, 439 U.S. 822, 99 S.Ct. 89, 58 L.Ed.2d 114 (1978). The questions raised in the December, 1982 report at 13 were satisfactorily answered not only by subsequent papers[4] but also by argument of counsel for both sides on January 4, 1983 at which time I found that defendants were not entitled to a hearing.[5] Consideration was also given to defendants' January 13, 1983 letter which requested reconsideration of my January 4th determination but I am still unpersuaded that the defendants have advanced sufficient evidence of the government's bad faith so as to warrant an evidentiary hearing on the matter.[6]

I find that the government conducted its investigations pursuant to a valid administrative scheme and not for the purpose of gathering evidence. Further, I find that the government made its decision to prosecute the defendants for violations of the Federal Food, Drug and Cosmetic Act of 1938 discovered at the July, 1976, March-April, 1977 and July, 1977 inspections on September 18, 1978.[7] I also find that the decision to prosecute the defendants for violations of the Federal Food, Drug and Cosmetic Act discovered at the January, 1979 inspection was made on November 21, 1979. Such findings undermine defendants' contention that the government had decided to prosecute the defendants prior to its inspections and had used the inspections as an evidence-gathering device.

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4. *See* note 3 *supra*.

5. *See* January 4, 1983 transcript at 5-6.

6. *See* January 19, 1983 transcript at 10.

7. *See* January 4, 1983 transcript at 4.

2. Concerning defendants' motion that Counts 8, 9 and 10 of the Information be dismissed,[8] I recommend that defendants' motions to suppress the evidence gathered at the January, 1979 inspection and to dismiss Counts 8, 9 and 10 which stem therefrom be denied. I find that the January, 1979 inspection was conducted in good faith pursuant to a November, 1978 work plan although such plan was not completed until January, 1979. Further, I find that the inspection was not conducted by the government for the purpose of gathering evidence to buttress its September, 1978 prosecution recommendation but, rather, was part of a valid administrative scheme.[9]

3. Concerning defendants' motion to suppress records regarding the shipment and importation of certain foods under 21 U.S.C. § 373 (1946) with regard to the defendants Barry Engel and Andre Engel,[10] I recommend that the defendants' motion on this issue be denied. I find that the FDA investigators did not invoke the authority of Section 373 to gain access to the shipping records so as to trigger the immunity provisions of the statute.[11] This finding that the documents were not requested pursuant to Section 373 incorporates the finding that the records were shown to FDA investigators voluntarily, thereby eliminating all grounds for defendants' motion to suppress the documents.[12]

4. Concerning defendants' motion to quash the subpoena of Gel Spice corporate records regarding the shipment and importation of certain foods,[13] I recommend that defendants' motion

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8. *See* item 6 of the Report at 15-16.

9. *See* January 4, 1983 transcript at 4-5.

10. *See* item 10 of the Report at 20-24.

11. *See* January 20, 1983 transcript at 97; *see also* Report at 20-24.

12. *See* item 10 of Report at 20.

13. *See* item 9 of the Report at 20.

be denied. In their April 16, 1982 motion to quash, defendants' sole objection to the production of the documents was based on the following grounds:

> (a) The documents sought constitute records showing the movement in interstate commerce or the holding thereof during or after such movement of any food, drug, device, or cosmetic, within the meaning of 21 U.S.C. § 373, and thus cannot be used in a criminal prosecution of the person from whom obtained.
>
> (b) The Government is attempting to utilize a subpoena to circumvent the provisions of 21 U.S.C. § 373 to nullify the impact of any favorable ruling which this Court may render in defendants' motion to suppress the same documents which is presently pending before this Court.

Since I have already found that 21 U.S.C. § 373 was not invoked at the time the defendants first showed the interstate records to the FDA investigators,[14] the immunity it provides in a criminal prosecution to one who produces documents pursuant to Section 373 is not available to any of the defendants. Therefore, the issues raised above in subparagraphs (a) and (b) are now moot.

Furthermore, since the documents requested are corporate records and not the personal papers of either Barry Engel or Andre S. Engel, the protection of the fifth amendment against self-incrimination is not available to either the corporate defendant, Gel Spice, Inc., or the individual defendants, who also happen to be the custodians of those records as officers of Gel Spice. *See* report at 24; *see also Curcio v. United States*, 354 U.S. 118, 122, 77 S.Ct. 1145, 1148, 1 L.Ed.2d 1225 (1957); *United States v. O'Henry's Film Works*, 598 F.2d at 316; *cf. United States v. Guterma*, 272 F.2d 344 (2d Cir. 1959) (court quashed so much of subpoena that requested personal books and records of the defendant). A corporate officer may not claim the personal privilege against compulsory self-incrimination with regard to corporate records even if those records

14. *See* section 3 *supra*.

might incriminate him personally. *Bellis v. United States*, 417 U.S. 85, 88-90, 94 S.Ct. 2179, 2182-2184, 40 L.Ed.2d 678 (1974); *United States v. MacKey*, 647 F.2d 898, 900 (9th Cir. 1981).

The preceding analysis should dispose of defendants' motion to quash. However, at the January 20th hearing the court *sua sponte* raised the issue of whether or not an individual defendant against whom there is an outstanding information or indictment can be compelled to deliver pursuant to a subpoena evidence that would establish the essential elements of the charges against him. The undersigned requested the parties to brief this issue at the close of the January 20th hearing.

After reviewing the correspondence from both sides,[15] I am persuaded that a defendant may be compelled to produce documents pursuant to a subpoena after an information has been filed even though the documents may be used as evidence against him. *See United States v. MacKey*, 647 F.2d at 901; *United States v. Berrios*, 501 F.2d 1207, 1212 (2d Cir. 1974) (material produced pursuant to a Rule 17(c) subpoena is that which would tend to establish the elements of a charge or defense); *United States v. Woodner*, 28 F.R.D. 22 (S.D.N.Y. 1961), *aff'd*, 317 F.2d 649 (1963); *United States v. Eli Lilly & Co.*, 24 F.R.D. 285 (D.N.J. 1959); *United States v. Gross*, 24 F.R.D. 138 (S.D.N.Y. 1959); *In re Investigation of World Arrangements, etc.*, 13 F.R.D. 280, 283 (D.D.C. 1952). The fact that after an information has been filed evidence is requested pursuant to a subpoena that inculpates the defendant does not preclude its production and use as evidence. *United States v. Authement*, 607 F.2d 1129, 1131-32 (5th Cir. 1979).

One final issue must be resolved with regard to the defendants' motion to quash the government's subpoena, that of the validity of the subpoena itself. Defendants raised this issue for the very first time in their February 8, 1983 letter. Defendants claim that the subpoena was vague and overbroad and that the government has failed to demonstrate its need for the docu-

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15. *See* the government's January 26, 1983 letter and defendants' February 8, 1983 response.

ments. Although the government did not have the opportunity to address these issues, I will examine them briefly in the interest of expediency.

The subpoena at issue here was originally returnable on the date first set for trial, August 3, 1981, which date was subsequently postponed. At a March 22, 1982 hearing before the Honorable Joseph M. McLaughlin the court instructed the defendants to produce the subpoenaed materials within two weeks.[16] Defendants' motion to quash was dated April 16, 1982; the government filed its response on May 5, 1982.

Rule 17(c) of the Federal Rules of Criminal Procedure governs the use of subpoenas in criminal cases. Subsection (c) of that rule covers subpoenas of documentary evidence and provides that:

> A subpoena may also command the person to whom it is directed to produce the books, papers, documents or other objects designated therein. The court on motion made promptly may quash or modify the subpoena if compliance would be unreasonable or oppressive. The court may direct that books, papers, documents or objects designated in the subpoena be produced before the court at a time prior to the trial or prior to the time when they are to be offered in evidence and may upon their production permit [them] to be inspected by the parties and their attorneys.

The purpose of the rule is not to facilitate discovery but, rather, to enable one to obtain and inspect evidentiary material prior to trial. *See United States v. Nixon*, 418 U.S. 683, 698-99, 94 S.Ct. 3090, 3102-03, 41 L.Ed.2d 1039 (1974); *Bowman Dairy Co. v. United States*, 341 U.S. 214, 219-20, 71 S.Ct. 675, 678-79, 95 L.Ed. 879 (1951); *United States v. Cuthbertson*, 630 F.2d 139, 144 (3rd Cir. 1980), *cert. denied*, 449 U.S. 1126, 101 S.Ct. 945, 67 L.Ed.2d 113 (1981); *United States v. Marchisio*, 344 F.2d 653, 669 (2d Cir. 1965). Rule

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16. *See* government's Memorandum in Opposition to Defendants' Motion to Quash Subpoena n. 1 filed May 5, 1982.

17(c) is available for use by either party. *United States v. Woodner*, 28 F.R.D. at 23; *United States v. Gross*, 24 F.R.D. at 141; 2 Wright, *Federal Practice and Procedure* § 274 (1982).

The court upon motion made promptly may quash or modify a subpoena if compliance would be either unreasonable or oppressive. Fed.R.Crim.P. 17(c); *United States v. Nixon*, 418 U.S. at 698, 94 S.Ct. at 3102; *In re Special Grand Jury No. 81-1*, 676 F.2d 1005, 1010 n. 5 (4th Cir. 1982). Defendants have made no claim that the government's request is either unreasonable or oppressive. The documents sought relate to the shipment, receipt and/or payment by Gel Spice for foods traveling in interstate commerce and received by the defendants on ten separate occasions. The government's request appears to encompass a minimal number of documents that have already been reviewed by the FDA since the government was given access to these records during the various inspections.

Materials produced pursuant to a subpoena may be provided at trial or prior to trial. A subpoena returnable on the day of trial may be issued without leave of court. *United States v. Van Allen*, 28 F.R.D. 329, 334 (S.D.N.Y. 1961). However, it is within the discretion of the trial court whether or not to order production of subpoenaed materials prior to trial. *United States v. Nixon*, 418 U.S. at 702, 94 S.Ct. at 3104; *United States v. MacKey*, 647 F.2d at 901; *United States v. Lieberman*, 608 F.2d 889, 904 (1st Cir. 1979), *cert. denied*, 444 U.S. 1019, 100 S.Ct. 673, 62 L.Ed.2d 649 (1980); *United States v. Berrios*, 501 F.2d at 1212. Such decision will be disturbed on appeal only where the action was clearly arbitrary or without support in the record. *United States v. Nixon*, 418 U.S. at 702, 94 S.Ct. at 3104.

If the subpoena were still a trial subpoena, there would be no question that the defendants would be required to produce the documents requested on the day of trial. However, at the March 22, 1982 hearing before Judge McLaughlin, the government requested that the documents be produced *prior to trial* pursuant to Fed.R.Crim.P. 17(c).[17]

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17. *See* note 15 *supra*.

In order to obtain documents prior to trial the party making the request must demonstrate the following:

(1) that the documents sought are evidentiary and relevant;

(2) that they are not otherwise procurable in advance of trial by the exercise of due diligence;

(3) that the party cannot properly prepare for trial without such production and inspection in advance of trial and the failure to obtain such inspection may tend unreasonably to delay the trial; and

(4) that the application is made in good faith and is not intended as a general fishing expedition.

United States v. Nixon, 418 U.S. at 699-700, 94 S.Ct. at 3103-3104 *citing United States v. Iozia*, 13 F.R.D. 335, 338 (S.D.N.Y. 1952); *United States v. Witt*, 542 F.Supp. 696, 697-98 (S.D.N.Y. 1982). The movant must establish the relevancy and admissibility of the records sought and specify the documents with reasonable particularity. *United States v. Nixon*, 418 U.S. at 700, 94 S.Ct. at 3103. The test for enforcement of a pretrial subpoena is whether the subpoena represents a good faith effort to obtain relevant evidence or a fishing expedition to expand discovery. *Bowman Dairy Co. v. United States*, 341 U.S. at 220-21, 71 S.Ct. at 678-79; *United States v. Cuthbertson*, 630 F.2d at 144.

Although the government bears the burden with regard to pretrial production of the subpoenaed documents, it did not have the opportunity to address the various issues since the defendants raised the question of the subpoena's validity at such a late date. Accordingly, the undersigned will attempt to ascertain whether or not the government has already satisfied its burden from the record already developed.

There is no doubt that the documents in question are relevant since they relate to the charges in the Information. *See United States v. Gross*, 24 F.R.D. at 140. Through their use the government will attempt to establish the fact that the foods

inspected at the Gel Spice premises traveled in interstate and/or foreign commerce, an essential element of the charge brought under 21 U.S.C. § 331(k) (Supp.II 1949) which prohibits any act that results in the adulteration of food that is being held for sale after shipment in interstate commerce.

Contrary to the defendants' claim that the "subpoena is overly broad and does not request specific documents,"[18] the government has tailored its request to records concerning ten discrete shipments of goods, thereby specifying its request with reasonable particularity. *See In re Rabbinical Seminary, etc.*, 450 F.Supp. 1078, 1084 (E.D.N.Y. 1978). Each set of documents is clearly identified so that their production will not be burdensome. Furthermore, it would appear that the documents are admissible as records kept in the ordinary course of doing business. Fed.R.Evid. 803(6); *see also United States v. Gross*, 24 F.R.D. at 141.

Although the government has not claimed that the materials are not available from any other source, the fact that they deal with shipments of goods from or through firms located outside the United States would make it impossible for the government to obtain the records since this court would have no jurisdiction over such companies. Additionally, although the government has not stated it must have the documents prior to trial, in view of the fact that the original trial was scheduled to start almost two years ago, production of the documents now would facilitate the trial once commenced, thereby fulfilling the purpose of Fed.R.Crim.P. 17(c), i.e., to expedite trials by requiring production of evidence beforehand. *Bowman Dairy Co. v. United States*, 214 U.S. at 220, 71 S.Ct. at 679.

Finally, I find that the government's motion was made in good faith since it was made for the purpose of obtaining evidence for use at trial and not for the purpose of unearthing additional documentary evidence. *See United States v. Gross*, 24 F.R.D. at 141. The government has long been aware of the existence of the documents, having examined the records during the various inspections.

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18. *See* letter of February 8, 1983.

5. Concerning defendants' motion to suppress statements made by Barry Engel and Andre S. Engel during the various investigations on the ground that such statements were coerced,[19] I recommend that defendants' motion to suppress be denied since I find that defendants' statements were voluntarily made during lawful inspections. Since defendants were not in custody, *Miranda* warnings were not required. *See United States v. Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532, 543 (8th Cir. 1981), *cert. denied,* 455 U.S. 1016, 102 S.Ct. 1709, 72 L.Ed.2d 133 (1982). Furthermore, the inspections were conducted pursuant to lawful authority and were consistent with the requirements of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 374 (1976). Prior to each inspection FDA personnel produced credentials and presented a written notice of inspection to either Andre S. Engel or Barry Engel.

Defendants have submitted no evidence that FDA personnel coerced them into making statements or used threats of any kind. Rather, defendants consented to each of the inspections at issue. Additionally, the reports of those investigations indicate that the defendants were generally cooperative. It is hard to believe that the owners of a corporation which has been in business for approximately twenty-five years would be intimidated so easily by FDA personnel. In fact, Barry Engel testified at the January 19th hearing that he refused to sign a statement drafted by an FDA investigator because Mr. Engel did not agree with its contents.[20]

6. Concerning defendants' motion to suppress statements made in the course of hearings conducted pursuant to 21 U.S.C. § 335 (1958) (also known as a "§ 305 hearing"), I recommend that defendants' motion to suppress be denied.[21] Three hearings were held on October 27, 1976, December 20, 1977 and May 30, 1979 in order to give defendants an opportunity to explain why criminal action should not be taken against

19. *See* item 11 of the Report at 24.

20. *See* January 19, 1983 transcript at 122-24.

21. *See* January 20, 1983 transcript at 42.

them for violation of the Federal Food, Drug and Cosmetic Act. *See* 21 U.S.C. § 335; 21 C.F.R. § 7.84 (1982). Prior to each hearing defendants received a notice of hearing, an information sheet describing the purpose and format of the hearing and a list of the adulterated foods that were the subject of the hearing.[22]

I find that defendants were aware of the possible consequences of the hearing (i.e., criminal prosecution) because the hearing notice advised them of that fact. Andre Engel appeared at the first § 305 hearing on October 27, 1976 and again at the second hearing at which time he requested an adjournment in order to return with counsel. Barry Engel, accompanied by counsel, represented Gel Spice and the individual defendants at the second hearing on December 20, 1977 and then again on May 30, 1979.

Since the defendants have failed to show that the government had already decided to prosecute them before the § 305 hearings were held,[23] I find that the statements made at the § 305 hearings were not taken in violation of the defendants' constitutional rights and, therefore, the evidence gathered therefrom should not be suppressed. *See United States v. Andreadis*, 234 F.Supp. 341, 347-49 (E.D.N.Y. 1964).

Objections to the findings and recommendations made herein and in the December 13, 1982 report shall be filed with the Honorable Joseph M. McLaughlin no later than August 1, 1983.

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22. *Id.* at 51-52.

23. *See* pp. 2-3 *supra*.

INTERIM REPORT AND RECOMMENDATION

December 13, 1982

The Honorable Joseph McLaughlin has referred the defendants' motions to dismiss the information to the United States Magistrate for a report and recommendation.

The defendants were charged in a ten count information alleging, in substance, that the defendants permitted food to become adulterated within the meaning of 21 U.S.C. §§ 342(a)(3) and 342(a)(4) (1946). The information was brought against Gel Spice, Inc., its president, Barry Engel, and its vice-president, Andre Engel.

Gel Spice, Inc. has been the subject of regular inspections by the Food and Drug Administration (FDA) since 1972 (Hile Affidavit ¶ 9). In July, 1976, March-April, 1977 and July 1977, inspectors from the FDA conducted three extensive inspections of the Gel Spice warehouse in Brooklyn, New York. Photographs were taken at the inspections and seizures were made of certain lots of adulterated foods. Pursuant to the Federal Food, Drug and Cosmetic Act (F, D & C Act) of 1938, § 305, 21 U.S.C. § 335 (1958), defendants were given the opportunity to present their views to the FDA at a section 305 hearing on October 27, 1976 following the July, 1976 inspection and on December 20, 1977 following the March-April and July, 1977 inspections. On September 18, 1978, the FDA Chief Counsel formally referred a request for prosecution of Gel Spice to the United States Department of Justice (DOJ), Office of the United States Attorney (Hile Affidavit ¶ 15). In January, 1979, consistent with its regulatory work plans, the FDA conducted a fourth inspection of the Gel Spice premises which also disclosed an active rodent infestation (Hile Affidavit ¶ 16). Another section 305 hearing was held following that inspection on May 30, 1979. The information was filed in December, 1980.

The defendants have brought various motions to suppress evidence and to dismiss certain counts of the information. The undersigned held a hearing on May 5, 1982 to resolve the

issues. A second hearing was held on June 29, 1982 during the first part of which the undersigned conducted an *in camera* review of various government documents out of the presence of the defendants but with counsel for the government present.[1]

The purpose of the *in camera* review was to determine if certain FDA documents were, in fact, privileged, and therefore, not subject to discovery by the defendants, as well as to ascertain the good faith of the government.

Defendants had sought disclosure of the documents in order to establish their claim that the FDA had acted in bad faith during its inspections of the Gel Spice premises, i.e., the FDA was not merely performing its regulatory function of administering the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-392 (1946) but, rather, was gathering evidence for preordained criminal prosecution of the defendants.

Before turning to the issues of privilege and good faith, the undersigned will dispose of other matters raised by the defendants in their multiple motions to suppress and dismiss.

ISSUES RESOLVED ON MAY 5, 1982

1. First, the defendants have moved to suppress the photographs taken by the FDA inspectors during the inspections on the ground that they are inflammatory and, therefore, unfairly prejudicial. In addition the defendants argue that the photographs were not taken in a reasonable manner and, therefore, should not be admissible.

The FDA inspections of Gel Spice, Inc. were conducted pursuant to 21 U.S.C. § 374 (1976) which provides a flexible standard of reasonableness to define the contours of an FDA inspection. The FDA's *Inspection Operations Manual* instructs inspectors that "[g]ood photographs are one of the most effective and useful forms of evidence of a violation."[2] Under

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1. A transcript of the conversations between the Magistrate and counsel for the Government has been prepared and filed under seal.

2. See Defendants' Memorandum of Law filed August 5, 1981, Appendix; *(FDA) Inspection Operations Manual* ¶ 523.

the circumstances present in this case, the photographing of the warehouse conditions by FDA agents was not unreasonable. The agents were in the warehouse pursuant to lawful authority and followed all procedural requirements mandated under 21 U.S.C. § 374. The photographs were taken as part of the inspection and the inspectors made no effort to conceal the fact that photographs were being taken (Hile Affidavit ¶ 19). In addition, the photographs are not suppressible under Rule 403 of the Federal Rules of Evidence since the probative value of the photographs are not, at this time, outweighed by the danger of unfair prejudice. The standard to be used is whether the photographs accurately depict the scene at a particular point in time. The photographs were taken during the normal course of the investigation. There is no evidence that the photographs contain distortions. In addition, a proper foundation must be established before the photographs can be admitted at trial, and the defendants will have the opportunity to cross examine the investigator through whom the photographs are offered. This will provide the defendants with ample protection. For these reasons, I recommend that the motion to suppress the photographs be denied.[3]

2. The defendants have also moved to dismiss count IV of the information, which charges the defendants with the adulteration of the spice marjoram, on the ground that the statute of limitations has run. The controlling statute, 18 U.S.C. § 3282 (1976), provides that the information must be instituted within five years after the offense is committed. The defendants claim that because the information states that the marjoram became adulterated in September, 1974 and the information was filed December 4, 1980, the statute of limitations has run. Count IV charges the defendants with a violation of 21 U.S.C. § 331(k) (Supp. II 1949) and 21 U.S.C. § 342(a)(4). These statutes prohibit the "holding" or "storing" of food under insanitary conditions whereby it may have become contaminated. Thus, as long as the information was

3. See May 5, 1982 transcript at 23-25.

drawn within a five year period after any time the marjoram was held for sale in an adulterated state, the statute of limitations does not preclude a prosecution. *United States v. Wiesenfeld Warehouse Co.*, 376 U.S 86, 84 S.Ct. 559, 11 L.Ed.2d 536 (1964). Since the offense charged is within the time allowed by the statute of limitations, I recommend that the defendants' motion to dismiss Count IV be denied.[4]

3. Defendants also move to dismiss certain counts of the information on the ground that the information charges the same offense in more than one count and is, therefore, multiplicitous. The defendants assert that because there were four investigations of the Gel Spice premises, there should be only four counts in the information.

Neither the United States Supreme Court nor the Second Circuit has spoken directly on this issue. The Northern District of New York has held, however, that one unsanitary condition can lead to multiple convictions based on different foods. *United States v. J. Treffiletti & Sons*, 496 F.Supp. 53, 56 (N.D.N.Y. 1980). Other circuits have reached similar results. *Akin Distributors v. United States*, 399 F.2d 306, 307 (5th Cir. 1968), *cert. denied*, 394 U.S. 905, 89 S.Ct. 1013, 22 L.Ed.2d 216 (1969); *United States v. H.B. Gregory Co.*, 502 F.2d 700 (7th Cir. 1974), *cert. denied*, 422 U.S. 1007, 95 S.Ct. 2629, 45 L.Ed.2d 670 (1975). In addition, although the multiplicity of counts was not an issue, the Supreme Court reversed the trial court's dismissal of a similar information in *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. at 87 n. 3, 84 S.Ct. at 561 n. 3. The general test for whether two violations constitute the same or different offenses is whether each violation requires proof of an additional fact that the other does not. *Blockburger v. United States*, 284 U.S. 299, 304, 52 S.Ct. 180, 182, 76 L.Ed. 306 (1932).

The ten counts in this case involve different foods, labeled differently, manufactured in different countries and shipped to the defendants on different dates. Clearly, the possibility exists that each count requires proof of additional facts. For these

4. See May 5, 1982 transcript at 49-50.

reasons, I recommend that the defendants' motion to strike various counts of the information be denied.[5]

4. The defendants also move to suppress all of the evidence obtained during the investigation because the investigations were conducted without a warrant. The warrantless inspection was authorized by 21 U.S.C. § 374, which provides that upon presenting credentials and a written notice to the owner, FDA agents can enter and inspect warehouses at reasonable times and within reasonable limits. Before all of the inspections, the inspectors presented their credentials and issued a notice of inspection (Hile Affidavit ¶ 19). I find that the inspections were clearly at reasonable times and within reasonable limits.

Further, there is no authority that would indicate that 21 U.S.C. § 374 is unconstitutional. Rather, the Supreme Court has held that public interest justifies warrantless inspections in closely or pervasively regulated industries. *United States v. Biswell*, 406 U.S. 311, 92 S.Ct. 1593, 32 L.Ed.2d 87 (1972) (warrantless inspections of firearms); *Colonnade Catering Corp. v. United States*, 397 U.S. 72, 90 S.Ct. 774, 25 L.Ed.2d 60 (1970) (warrantless inspections of liquor). In *Marshall v. Barlow's Inc.*, 436 U.S. 307, 98 S.Ct. 1816, 56 L.Ed.2d 305 (1978), the court held warrantless OSHA inspections to be unconstitutional, but expressly recognized the *Biswell-Colonnade* exception and noted that industries other than liquor and firearms may be within the exception. *Id.* at 313, 98 S.Ct. at 1821.[6]

Public interest is deeply involved in the food industry. Undetected violations could adversely affect public health and well-being. Given the pervasive nature of the federal regulation of the food and drug industry, in contrast to the situation in *Barlow's*, warrantless inspections pursuant to § 374 are fully

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5. See May 5, 1982 transcript at 69.

6. The mining industry is one that comes within the *Biswell-Colonnade* exception. *Donovan v. Dewey*, 452 U.S. 594, 101 S.Ct. 2534, 69 L.Ed.2d 262 (1981) (warrantless inspection of mine did not violate the fourth amendment).

consistent with the fourth amendment. *United States v. New England Grocers Supply Co.*, 488 F.Supp. 230, 238 (D.Mass. 1980). *See also United States v. Jamieson-McKames Pharmaceuticals*, 651 F.2d 532 (8th Cir. 1981), *cert. denied*, 455 U.S. 1016, 102 S.Ct. 1709, 72 L.Ed.2d 133 (1982); *cf. United States v. Gordon*, 655 F.2d 478, 482-84 (2d Cir. 1981) (warrantless search pursuant to New York State Insurance Law did not violate the fourth amendment). Since a warrant was not necessary to conduct the inspections of the Gel Spice warehouse, I recommend that defendants' motion to suppress the evidence gathered therefrom be denied.[7]

GOOD FAITH ON THE PART OF THE FDA

5. The remainder of defendants' motions are dependent upon the determination of whether the investigations occurred in furtherance of a criminal investigation rather than for administrative purposes. A finding must be made, therefore, as to when the institutional decision was made to prosecute the defendants. The FDA, in its own affidavit, asserts that in February, 1977 the New York District forwarded a prosecution recommendation to the Bureau of Foods. The Bureau of Foods concurred, and forwarded the recommendation to the Office of the Commissioner of the FDA, who then forwarded the recommendation to the FDA's Office of General Counsel (Hile Affidavit ¶ 13). On September 18, 1978, the FDA Chief Counsel referred the agency's request for prosecution of Gel Spice to the United States Department of Justice, Office of the United States Attorney, Eastern District of New York. According to the Government the referral constituted the agency's first formal institutional decision to prosecute. (Hile Affidavit ¶ 15). Defendants, on the other hand, contend that the decision to prosecute them occurred much earlier, if not as early as 1972.[8] If this were true, one could question whether or not

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7. See May 5, 1982 transcript, at 16-17.

8. See Defendants' Memorandum of Law filed October 19, 1982 at 6.

subsequent inspections were conducted for regulatory purposes or as evidence-gathering forays.

At the May 5, 1982 conference I indicated that it might be necessary to take testimony on the issue of the FDA's good faith with regard to the various inspections.[9]

On June 29, 1982 I reviewed *in camera* the cover sheets which were prepared by FDA investigators and which accompanied the official reports of their inspections, as well as other internal memoranda. The purpose of such review was to determine not only the relevance of those documents to the issue of the government's good faith but also whether or not said documents were privileged.[10] A second conference was held later that day with counsel for both sides present; both meetings were recorded.

After reviewing the documents in the presence of FDA counsel and personnel, the undersigned made a tentative determination that the decision to prosecute the defendants was made on September 18, 1978.[11] Such a finding would preclude a claim of bad faith on the FDA's part with regard to the 1976 and 1977 inspections. However, I reserved decision with respect to the 1979 inspection and asked counsel to brief the following points:

> (a) Assuming the January, 1979 inspection was conducted in accordance with a bona fide administrative scheme, must the evidence obtained therefrom be suppressed for all purposes and/or should counts 8, 9 and 10 be severed or dismissed because of the prior decision to prosecute the defendants.
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> (b) Did the *in camera* review of the FDA documents deny defendants a confrontation of the evidence to be used against them, thereby requiring that they be given access to the documents reviewed.

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9. See May 5, 1982 transcript at 4, 6 and 13.

10. See May 5, 1982 transcript at 88-90, 98-99.

11. See June 29, 1982 transcript at 4-5.

After consideration of the memoranda and exhibits submitted by the parties subsequent to the June 29, 1982 conferences, the undersigned hereby withdraws his tentative determination that September 18, 1978 was the date on which the FDA first decided to institute a criminal prosecution of the defendants. Rather, the date of the commitment to prosecute together with the issue of the FDA's good faith in the conduct of its inspections, will be among the matters to be resolved at an evidentiary hearing to be held at 10:00 A.M. on January 4, 1983 as originally discussed on May 5, 1982. This hearing will give the defendants an opportunity to question FDA witnesses but defendants will not gain access to the documents submitted by the FDA under seal for the reasons outlined below.

A regulatory agency is empowered to investigate the possible violation of the laws it enforces through the use of administrative process provided that its inquiries are for a proper purpose, the information sought is relevant to that purpose and the statutory procedures are observed. *United States v. Powell*, 379 U.S. 48, 57-58, 85 S.Ct. 248, 254-255, 13 L.Ed.2d 112 (1964). Once the agency has established the above, the burden shifts to the one alleging bad faith on the agency's part to come forward with evidence of such bad faith. *See United States v. O'Henry's Film Works*, 598 F.2d 313, 320 (2d Cir. 1979).

At the May 5th meeting the undersigned made a determination that the defendants had the burden of coming forward with evidence of the FDA's bad faith in the conduct of its regulatory inspections.[12]

Bad faith exists where a regulatory agency employs administrative procedures solely for a criminal purpose. *United States v. LaSalle National Bank*, 437 U.S. 298, 316-17, 98 S.Ct. 2357, 2367-68, 57 L.Ed.2d 221 (1978); *Securities and Exchange Commission v. Dresser Industries, Inc.*, 628 F.2d 1368, 1387 (D.C.Cir. 1980) (en banc), *cert. denied*, 449 U.S. 993, 101 S.Ct. 529, 66 L.Ed.2d 289 (1980); *United States v. Schutterle*, 586 F.2d 1201, 1203 (8th Cir. 1978). In order to secure an

12. See May 5, 1982 transcript at 11.

evidentiary hearing and/or discovery of the FDA documents, the defendant must make a substantial preliminary showing of bad faith. *United States v. O'Henry's Film Works*, 598 F.2d at 320; *United States v. Morgan Guaranty Trust Company*, 572 F.2d 36, 43 n. 9 (2d Cir.), *cert. denied sub nom. Keech v. United States*, 439 U.S. 822, 99 S.Ct. 89, 58 L.Ed.2d 114 (1978); *United States v. Morgan Guaranty Trust Co.*, 524 F.Supp. 24, 27 (S.D.N.Y. 1981). Further, defendants "bear the burden to disprove the actual existence of a valid civil . . . purpose . . ." *LaSalle*, 437 U.S. at 316, 98 S.Ct. at 2367. However, an evidentiary hearing is not required in the absence of a meaningful and substantial factual showing of an improper purpose by the investigative agency. *Securities and Exchange Commission v. Howatt*, 525 F.2d 226, 229 (1st Cir. 1975).

After careful consideration the undersigned will permit the defendants to explore the issue of the FDA's good faith in order to resolve the following questions. *See Securities and Exchange Commission v. Knopfler*, 658 F.2d 25, 26 (2d Cir. 1981), *cert. denied sub nom. Sprecher v. Securities and Exchange Commission*, 455 U.S. 908, 102 S.Ct. 1255, 71 L.Ed.2d 446 (1982) (evidentiary hearing within trial court's discretion). First, the Hile Affidavit of May 15, 1981 does not adequately explain the delay between the February, 1977 prosecution recommendation by the New York District Office and the September 18, 1978 referral to the United States Attorney. *See LaSalle*, 437 U.S. at 316-317, 98 S.Ct. at 2367-2368. A second prosecution recommendation was made on Jul 17, 1979 which was referred to the United States Attorney on November 21, 1979 (Hile Affidavit ¶ 18).[13]

Furthermore, the Hile Affidavit is ambiguous with respect to the February, 1973 prosecution recommendation (Hile Affidavit ¶ 10). It is unclear whether that recommendation was

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13. It should be noted that more than four years elapsed from the time of the first inspection in July, 1976, and the filing of an information against defendants on December 4, 1980.

withdrawn or just held in abeyance as some of the subsequent Establishment Inspection Reports (EIR) seem to indicate.[14]

The issue of the FDA's bad faith is inextricably entwined with the date on which the FDA decided to prosecute the defendant. In *LaSalle* the date of referral by the Internal Revenue Service (IRS) to the Department of Justice constituted the initiation of the criminal prosecution.[15] 437 U.S. at 311, 98 S.Ct. at 2365; *see also United States v. Schutterle*, 586 F.2d at 1203 nn. 4 and 5. The prosecution contends that the same rule should be applied in the instant action, i.e. September 18, 1978 and November 21, 1979 are the dates on which the FDA first decided to prosecute the defendants on Counts 1-7 and Counts 8-10, respectively. However, an agency may not delay referral to the DOJ for the purpose of gathering evidence for the subsequent criminal prosecution. *LaSalle*, 437 U.S. at 316-317, 98 S.Ct. at 2367-2368.

Should the FDA establish that the inspections were valid regulatory actions and conducted in good faith prior to a decision to prosecute the defendants, the evidence derived from those inspections should not be suppressed. In *United States v. Kordel*, 397 U.S. 1, 90 S.Ct. 763, 25 L.Ed.2d 1 (1970), the Supreme Court expressly authorized the FDA to proceed concurrently with civil and criminal actions when it refused to suppress civil interrogatories in a subsequent prosecution of the same case. *Kordel* recognized the need to investigate criminal as well as civil claims in order to protect the public interest and approved parellel investigations by a regulatory agency. *Id.* at 11, 90 S.Ct. at 679. The FDA regulatory inspections were proper unless it is established that the purpose was solely for investigatory, and not regulatory, purposes. *See United States v. Shaefer, Michael and Clairton Slag, Inc.*, 637 F.2d 200, 204 (3rd Cir. 1980).

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14. See July, 1976 EIR.

15. It appears that the multilayered review process undertaken by the IRS in *LaSalle* before recommending prosecution to the Department of Justice is very similar to that described in the Hile Affidavit at ¶ 6. See *LaSalle*, 437 U.S. at 315, 98 S.Ct. at 2366.

COUNTS 8, 9 AND 10 OF THE INFORMATION

6. Regardless of the date which is established as the point in time when the FDA was committed to prosecute the defendants on Counts 1-7 such date would be prior to the January, 1979 inspection.

If the FDA establishes that the January, 1979 inspection was part of a valid administrative scheme of enforcement of the Federal Food, Drug and Cosmetic Act, the undersigned sees no reason to dismiss those counts of the information resulting from that inspection, i.e., Counts 8, 9 and 10. If part of a valid work plan, such inspection would have been for regulatory purposes and not for use in the seven counts already referred to the Department of Justice.

Counts 8, 9 and 10 are based on separate and distinct inspection which revealed unsanitary conditions that existed in January, 1979 and which resulted in *additional* violations of the Food, Drug and Cosmetic Act.

It is absurd to expect that, once the FDA recommends criminal prosecution based on violations it has already uncovered, it can no longer carry out its regulatory duties. If the defendants are to be prosecuted on Counts 8, 9 and 10, such prosecution would be for conditions extant in 1979, not conditions that existed in July, 1976, March-April, 1977 or July, 1977.

In order to suppress the evidence from the 1979 inspection, it would have to be established that the FDA conducted that inspection solely for the purpose of gathering evidence to support its prior recommendation to the Department of Justice. *See LaSalle*, 437 U.S. at 316-17, 98 S.Ct. at 2367-68; *Abel v. United States*, 362 U.S. 217, 226, 230, 80 S.Ct. 683, 690, 692, 4 L.Ed.2d 668 (1960).

ACCESS TO FDA RECORDS

7. (a) In exploring the issue of the FDA's bad faith the defendant will not have the benefit of the documents submitted under seal by the FDA. *See LaSalle*, 437 U.S. at 304 n. 5, 98 S.Ct. at 2361 n. 5 (court reviewed IRS investigative files *in*

camera).[16] The documents in question include internal agency memoranda as well as notes made by investigators after inspections of the Gel Spice premises. These documents closely parallel those records already provided to defendants in discovery proceedings, i.e., Establishment Inspection Reports of the various Gel Spice investigations. After careful consideration of both sets of documents, the undersigned recommends that they not be disclosed to the defendants because they are cumulative in many respects. Further, the only additional material consists of analyses, opinions and recommendations by FDA employees which are not subject to disclosure under Fed.R.Crim.P. 16(a)(1)(C) since they were made during the investigation of the case. *See* Fed.R.Crim.P. 16(a)(2).

(b) In support of their petition for disclosure of the FDA internal records defendants cite *United States v. Berrios*, 501 F.2d 1207 (2d Cir. 1974), which affirmed the trial court's discretion after an *in camera* review to require production of materials relevant and probative to the defenses raised, even though the documents ordinarily would be exempt from disclosure under Fed.R.Crim.P. 16(a)(2). The test for disclosure of such exempt material is the "relevancy of the evidence to the specific defense for which it is sought. . . " *Id.* at 1212.

In *Berrios* the Second Circuit indicated that it would not have even ordered the government to produce the memorandum in question because (1) the defendant failed to make an adequate preliminary showing of relevancy and (2) defendant seemed to be embarking on a "fishing expedition." *Id.* at 1211.

Having reviewed the documents in question,[17] the undersigned is of the opinion that they are not demonstrably relevant

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16. Defendants claim that the documents are material to the preparation of their defense pursuant to Fed.R.Crim.P. 16(a)(1)(C). The Government resists disclosure under Fed.R.Crim.P. 16(a)(2) claiming that they are "reports, memoranda (and) other internal documents made by. . . government agents in connection with the investigation or prosecution of the case. . . . " *Id.*

17. Unlike *Berrios* where the trial court did not review the memorandum prior to its order to produce the document since the government refused to deliver it to the Court.

to the defendants' position, i.e., they would not tend to establish the elements of their defenses. *Id.* at 1212. Rather, the records sought would only serve to buttress the FDA's claims. The records already provided by the FDA contain sufficient information to enable the defendants to conduct a meaningful inquiry of FDA practices and procedures at the evidentiary hearing; there is no need to disclose internal FDA files.

(c) In further support of their request to gain access to the FDA internal records defendants cite *United States v. Saffaie, et al.*, Cr. No. 82-371-RPA (N.D.Cal. 1982), in which an indictment was dismissed by the trial court because the government refused to comply with its discovery order.

Saffaie can be distinguished from the instant case because the Government has, in fact, surrendered the documents to the undersigned who has reviewed them and concluded that they are either cumulative or not relevant to the defendants' position.

(d) Finally, the undersigned rejects defendants' claim that the documents they seek constitute *Brady* material since they are not exculpatory; the records reviewed do not go to the guilt or punishment of the defendants which is the standard for disclosure under *Brady v. Maryland*, 373 U.S. 83, 87, 83 S.Ct. 1194, 1196, 10 L.Ed.2d 215 (1963). The FDA has acknowledged its *Brady* obligation and there is no reason to doubt it will not honor that obligation. The FDA has fully complied with all discovery requests to date, save for the documents submitted under seal.

Non-Brady material is obtainable pursuant only to Fed.R.Crim.P. 16. *United States v. Kaplan*, 554 F.2d 577, 579-80 (3rd Cir. 1977). Since I have already determined that the records are exempt from disclosure under Rule 16, they will not be turned over to the defendants at this time.

Should the preparer of any record testify at the hearing mandated by this report this testimony will not compel an examination of such record as the testimony would not be *trial* testimony. *See* 18 U.S.C. § 3500(a).

The Government is directed to prepare an index of the documents it has submitted for inspection by the undersigned and is to serve that index on defendants within ten days of the receipt of this report. This index is to identify the preparer of each document to facilitate the defendants' identification of potential witnesses.

PREJUDICE TO DEFENDANTS

8. Defendants claim that they were prejudiced by the June 29, 1982 *in camera* review because FDA counsel and personnel were present. The purpose of the review was not to take *ex parte* testimony or to hear argument on the facts in issue.[18] Rather, FDA counsel and personnel were present only to answer any questions raised by the undersigned during the review.

Fed.R.Crim.P. 16(d)(1) permits a party to make an *ex parte* showing when seeking a protective order. It does not prohibit the presence of the party. The adversary's rights are protected by the fact that the text of the party's statement must be preserved in the event of an appeal. The June 29, 1982 *in camera* review was transcribed; further, the affidavit and documents submitted are still within the court's possession.

Additionally, in order to avoid any claim of prejudice to the defendants, the undersigned will not rely on any of the documents reviewed *in camera* on June 29, 1982 as the basis for findings to be made at the January 4, 1983 evidentiary hearing.

SUBPOENA DUCES TECUM

9 and 10. With regard to the defendants' motion to quash the subpoena *duces tecum* (9) served upon defendant Gel Spice, Inc. by the FDA on July 10, 1981 for the production of records relating to the shipment and importation of certain foods, I am withholding my recommendation pending testimony by defendants Barry Engel and Andre S. Engel. This issue is directly related to the question of whether or not the

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18. See May 5, 1982 transcript at 126.

interstate records were voluntarily surrendered by the defendants to FDA investigators (10) such matter being one of the issues reserved at the May 5, 1982 meeting for an evidentiary hearing.

Defendants resist production of the documents on the following grounds: (a) the documents constitute evidence of interstate commerce within the meaning of 21 U.S.C. § 373 (1946) and, thus, cannot be used in criminal prosecution against one who has supplied them; and (b) the records are currently the subject of a motion to suppress on the ground that they were not provided voluntarily by the defendants, Barry Engel and Andre S. Engel.

Although 21 U.S.C. § 373 was part of the original 1938 Federal Food, Drug and Cosmetic Act, there is very little case law dealing with this section. The section provides immunity in a criminal prosecution to one who has permitted FDA personnel to inspect records of interstate shipments after (a) the FDA has requested the records, (b) the custodian has refused to provide them and (c) the investigator has again requested the records specifically under the authority of 21 U.S.C. § 373 and has presented a written statement as required by that section. *United States v. Lyon Drug Co.*, 122 F.Supp. 597, 601 (E.D.Wisc. 1954); *United States v. Scientific Aids Co.*, 117 F.Supp. 588, 589 (D.N.J. 1954); *United States v. Arnold's Pharmacy, Inc.*, 116 F.Supp. 310, 314 (D.N.J. 1953). If the custodian has shown the documents to FDA investigators voluntarily, § 373 does not apply and one is not entitled to its immunity. *United States v. Herold*, 136 F.Supp. 15, 16 (E.D.N.Y. 1955); *United States v. Lyon Drug Co.*, 122 F.Supp. at 599-601. The question of voluntariness remains to be resolved at the evidentiary hearing and will determine whether or not the plaintiff can use the interstate records against the defendants in this criminal prosecution. *See United States v. Herold*, 136 F.Supp. at 16.

In support of its subpoena to obtain the interstate records the FDA contends that the immunity provided by § 373 is not available to the defendants because they are not carriers and cites the following legislative history:

> Carriers are required to make, available for copying, records showing interstate shipments of suspected articles so that Federal jurisdiction can be established. * * *
>
> Section 703 [21 U.S.C. § 373] requires interstate carriers and receivers to permit access to and the copying of all necessary records to show interstate shipment and thus establish Federal jurisdiction. This provision is necessary since some warehousemen and trucking concerns and even some railroads have refused to permit the copying of records which were essential to the institution of proceedings to control abuses of consumer health and welfare. The absence of such provision in the present law has been a definite handicap to its enforcement. * * * H.R.Rep. No. 2139 75th Cong.3d Sess. pps. 2, 12 (1938).

See also United States v. Arnold's Pharmacy, Inc., 116 F.Supp. at 314; *United States v. Lyon Drug Co.*, 122 F.Supp. at 600-01. However, the language of § 373 itself refers to "carriers engaged in interstate commerce and persons receiving food . . . in interstate commerce or holding such articles so received . . ." 21 U.S.C. § 373. The term "person," as defined in the Federal Food, Drug and Cosmetic Act, includes an individual partnership, corporation or association and, therefore, would apply to the defendant Gel Spice, Inc. *See* 21 U.S.C. § 321(e).

Although § 373 may have been enacted primarily to force carriers to permit FDA inspectors to gain access to their records of interstate shipment, a literal reading of the statute persuades me that the defendant Gel Spice is within the class of persons entitled to invoke the § 373 immunity.

Not only must carriers engaged in interstate commerce permit FDA inspectors to copy interstate records but "persons receiving food . . . in interstate commerce or holding such articles so received . . ." must also grant the FDA access. 21 U.S.C. § 373. Further, "it shall be unlawful for any such carrier or person to fail to permit such access . . . when such request is . . . in writing. . . ." *Id.* However, "evidence ob-

tained under this section . . . shall not be used in a criminal prosecution of the person from whom obtained." *Id.*

The only case within this district that has considered § 373 is *United States v. Herold, supra*, which stated that "evidence obtained pursuant to § 373 shall not be used in a criminal prosecution of the person from whom it is obtained." *Id.* at 16. *See also United States v. 75 Cases*, 146 F.2d 124, 127-28 (4th Cir. 1944); *United States v. Arnold's Pharmacy*, 116 F.Supp. at 313-14; *United States v. Maryland Baking Co.*, 81 F.Supp. 560, 562 (N.D.Ga. 1948).

None of the cases cited previously reached the issue of whether or not the defendant was within the class of persons entitled to invoke § 373 immunity. Rather, in each case the court found that since the interstate records were shown voluntarily to the FDA inspectors, § 373 did not apply. *See United States v. Lyon Drug Co.*, 122 F.Supp. at 600; *United States v. Scientific Aids Co.*, 117 F.Supp. at 589; *United States v. Arnold's Pharmacy*, 116 F.Supp. at 315. In *United States v. Herold*, although the government presented strong evidence that the defendants had consented and even cooperated in the copying of the interstate records, the Court granted the defendants a hearing on the question of voluntariness. *Id.* at 16.

In conclusion, in order to suppress the interstate records defendants must demonstrate at the hearing that they initially refused access to the FDA investigators and only permitted the investigators to inspect the records after a written request was made pursuant to § 373. Should the defendants fail to sustain their burden, the records will not be suppressed since company records are subject to production pursuant to a lawful subpoena. Fed.R.Crim.P. 17(c). As a corporate defendant Gel Spice is not entitled to claim the protection of the fifth amendment. *Wilson v. United States*, 221 U.S. 361, 382-84, 31 S.Ct. 538, 545-46, 55 L.Ed. 771 (1911); Wright, *Federal Practice and Procedure* § 274 (2d ed. 1982). The individual defendants cannot rely on the fifth amendment privilege to avoid production of the records of a collective entity which are in

their possession in a representative capacity, even if those records might incriminate them. *Bellis v. United States*, 417 U.S. 85, 88, 94 S.Ct. 2179, 2183, 40 L.Ed.2d 678 (1974).

A custodian of corporate records held in a representative capacity may be required not only to produce records in his custody but also testify regarding those records. *United States v. J. Tirocchi & Sons*, 187 F.Supp. 785, 787 (D.R.I. 1960). The production of corporate record may be obtained even in situations where the corporation is closely held or the "alter ego" of the owner. *United States v. Fago*, 319 F.2d 791, 793 (2d Cir. 1963).

Other issues to be addressed at the evidentiary hearing include (11) whether statements made by the defendants during the various investigations should be suppressed because they were coerced[19] and (12) whether statements made at the section 305 hearings pursuant to 21 U.S.C. § 335 should be suppressed.[20] Since the FDA has already provided the defendants with samples pursuant to 21 U.S.C. § 372, the only outstanding discovery matter is the production of 16(b) material by the defendants (13). (See accompanying order).

Whereas defendants have pending various motions to dismiss this prosecution and to suppress evidence, these matters having been referred to me pursuant to 28 U.S.C. § 636(b)(1)(B), and having reviewed the papers submitted and heard argument of both counsel at hearings on May 5, 1982 and June 29, 1982, I make the following findings and recommendations:

1. Concerning defendants' motion to suppress the photographs taken in the course of the various inspections, I recommend that defendants' motion on this issue be denied, with defendants having the right to raise the issue of undue prejudice at trial.

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19. See May 5, 1982 transcript at 26.

20. *Id.* at 35-39.

2. Concerning defendants' motion to dismiss Count IV on the ground that it is barred by the statute of limitations, I recommend that defendants' motion to dismiss be denied.

3. Concerning defendants' motion to dismiss certain counts of the Information on the ground that they are multiplicitous, I recommend that defendants' motion be denied.

4. Concerning defendants' motion to suppress evidence on the ground that warrantless inspections were conducted in violation of defendants' fourth amendment rights, I recommend that defendants' motion on this issue be denied.

5. Concerning defendants' motion to dismiss or suppress evidence on the ground that the government obtained evidence in bad faith, i.e., inspections were conducted to gather evidence for a pre-determined criminal prosecution, this matter will be resolved based on findings to be made at the January 4, 1983 evidentiary hearing.

6. Concerning defendants' motion that Counts 8, 9 and 10 of the Information be dismissed, this issue is partially dependent upon whether or not the January, 1979 inspection was conducted in good faith, which matters will be determined at the evidentiary hearing, together with the date on which the FDA first decided to prosecute the defendants as a result of this inspection. Should it be established that the investigation was bona fide, I recommend that defendants' motion to suppress the evidence and to dismiss counts 8, 9 and 10 be denied.

7. Concerning defendants' motion that they are entitled to internal FDA files (a) pursuant to Fed.R.Crim.P. 16(a)(1)(C) because they are material to the preparation of the defendants' defense and (b) the documents constitute *Brady* material, I recommend that defendants' motion on this issue be denied. I direct that the government provide defendants with an index of these documents identifying the preparers of the documents within ten days of its receipt of this report.

8. Concerning defendants' claim that they were prejudiced by the June 29, 1982 *in camera* review and denied the opportunity to confront the evidence against them, I find that the defendants were not prejudiced by the procedure, in light of the fact that the undersigned will rely on none of the documents reviewed as the basis for any determination made at the evidentiary hearing, nor were the defendants denied an opportunity to confront the evidence against them since they are already in possession of the necessary documents.

9 and 10. Concerning defendants' motion to quash the subpoena of Gel Spice corporate records regarding interstate shipments (9) and defendants' motion to suppress interstate shipping documents under 21 U.S.C. § 373 with regard to the defendants Barry Engel and Andre S. Engel (10), I am reserving decision on these matters pending testimony at the evidentiary hearing.

11. Concerning defendants' motion to suppress statements made by Barry Engel and Andre S. Engel during the various investigations on the ground that they were coerced, I am withholding my recommendation pending testimony at the evidentiary hearing.

12. Concerning defendants' motion to suppress statements made in the course of hearings conducted pursuant to 21 U.S.C. § 335, this matter has been reserved pending testimony at the evidentiary hearing.

13. Concerning defendants' requests for discovery as set forth in their letters of February 20, 1981 and April 2, 1982, I find that all of the listed items have been supplied by the Government. The only outstanding matter is the production of 16(b) material by the defendants which material shall be produced in accordance with the accompanying order of this date.

The time within which objections may be filed to the findings and conclusions contained herein will begin to run at such time as I render my final report after the conclusion of

the hearing ordered in this report. To insure that the record accurately reflects certain prior decisions by this Court, pursuant to 28 U.S.C. § 636 the following discovery orders were made at the hearings on May 5, 1982, and June 29, 1982:

1. The government was ordered to:

   a. Supply a bill of particulars by May 31, 1982, which will state (in generic terms with incorporation by reference of discovery materials provided to defendants) the acts which the government contends were done by Barry Engel and Andre S. Engel to render the food alleged in each count of the Information to become adulterated.

   b. List the names, addresses, and curricula vitae of all expert and FDA witnesses the government intends to call at trial.

2. Defendants were ordered by August 15, 1982, to furnish the government all material required by Rule 16(b) of the Federal Rules of Criminal Procedure.